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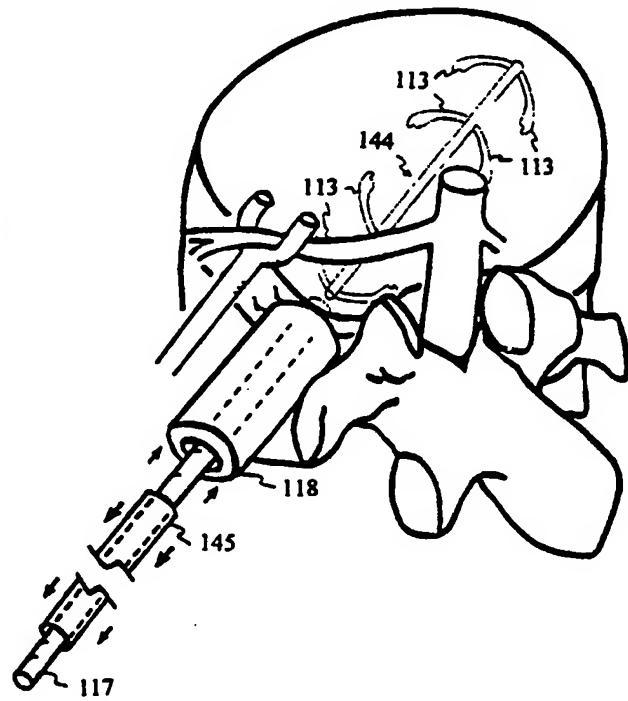
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(57) Abstract: A tissue-fastening device with counter gripping resilient anchors folded within a needle is delivered through bulging tissue into the intervertebral disc. The bulge is then compressed, a plunger is held stationary behind the fastener while the needle is withdrawn. As the restriction of the needle is removed, the resilient anchors open, counter fastening the annular tissues across the central disc by both ends of the tissue fastener. Since the anchors open within the compressed bulge, the previously bulging annulus is mechanically anchored and fastened down by the tissue fastener, free from impinging the adjacent nerve. A toggle and a disc restraining device are also proposed to compress bulging discs. To decompress bulging discs, a disc drain tube containing inlet and outlet openings, with pressure-regulating capabilities, drains nucleus pulposus from a swollen intervertebral disc to alleviate low back pain.

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INTERVERTEBRAL DISC REPAIR

Jeffrey E. Yeung

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FIELD OF INVENTION

This invention relates to devices and methods for fastening bulging, herniated or compressed discs and torn tissues with mechanical devices. This invention also covers devices and methods for draining nucleus pulposus to ease low back pain.

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BACKGROUND, TRADITIONAL SURGICAL PRACTICES AND
PRIOR INVENTIONS

Low Back Pain

Low-back pain is one of the most prevalent, costly and debilitating ailments afflicting mankind. Seventy to eighty-five percent of all people have back pain at some time in their life. 15 Symptoms are most common among middle-aged adults and are equally common in both men and women. Back pain related to disc disorders, however, is more prevalent among men. The recurrence rate of low back pain ranges from 20% to 44% annually, with lifetime recurrences of 85% (National Institute of Health Guide, Vol. 26, 16, May 16, 1997).

Low back pain is very costly to patients, our health care system and society. For many, no 20 position can ease their pain or numbness, not even bed rest. It is often the reason for decreased productivity due to loss of work hours, addiction to pain-killing drugs, emotional distress, prolonged hospital stays, loss of independent living, unplanned early retirements and even financial ruin. Each year in the US, about 2% of the work force have back injuries covered by worker's compensation, with about \$12 billion spent directly on medical costs in 1994.

25 Most back pain is caused by a defect or damage in the intervertebral disc. The disc is comprised of nucleus pulposus and annulus. The nucleus pulposus is highly gelatinous with a composition of 70-90% water, 25-60% proteoglycan (dry weight) and 10-20% collagen (dry weight). The function of the nucleus pulposus is to sustain prolonged compression during the day and to resiliently re-inflate and reestablish disc height during the night. The pulposus is retained 30 and surrounded by layers of cartilaginous annulus. Together the pulposus and the annulus behave as a resilient cushion. In the erect position, the weight of the body constantly compresses upon a stack of these cushions alternating between a series of vertebrae. During constant compression,

the pulposus in each disc also behaves as a water reservoir, which is slowly and constantly being squeezed and drained of its water content through the end plates connected to the vertebrae. As a result, the disc height decreases throughout the day. During bed rest, the weight of the body no longer compresses the disc. Due to the water absorbing nature of the nucleus pulposus, the flow 5 of water is now reversed from the vascular vertebrae back into the proteoglycan and collagen. As a result, the disc height is reestablished, ready to provide support for another day.

Under dynamic conditions, the gelatinous nucleus pulposus exhibits predominantly solid-like behavior with values for dynamic modulus ranging from 7 to 20 kPa (J.C. Iatridis et. al., J. Biomechanics, Vol. 30, No. 10, 1005-1013, 1997). With aging and degeneration, the viscoelastic 10 property of the nucleus pulposus undergoes a transition from fluid-like to solid-like behavior (J.C. Iatridis et. al., Journal of Orthopaedic Research, 15:318-322, 1997). As a result, both the resiliency and disc height diminish.

Some causes that contribute to low back pain are classified. Type I: Acute back sprain involves damage to ligaments, muscles or even the vertebral end plates from physical overload. 15 Type II: Organic idiopathic spine pain occurs from increased fluid uptake by the disc. Type III: Posterolateral annulus disruption of annular fibers irritates nerves associated with the sacroiliac region, buttock and the back of the thigh. This situation may resolve itself through reabsorption or neutralization by phagocytosis of the disrupted annular fibers. Type IV: Nerve root irritation by the bulging disc leads to sciatica. This type of disc protrusion is traditionally repaired surgically by 20 tissue removal, chemonucleolysis or percutaneous discectomy. Type V: Nerve irritation by wandering sequestered disc material has unpredictable exacerbation and remissions. Type VI: Sequestrum of the annulus and/or nucleus into the spinal canal or intervertebral foramen results in nerve irritation from inflammation, mechanical pressure, chemical irritation, autoimmune response or combinations of irritants. Type VII - A degenerated disc, with substantial decrease in 25 mechanical properties, is often associated with pain and disability.

The most common reason for recurrent pain is the bulging or herniation of an intervertebral disc. The traditional surgical treatment for a bulging or herniated disc is a series of tissue removing, filling and supporting procedures: (1) laminectomy, removal of lamina from the vertebra which covers part of the herniated disc, (2) discectomy, removal of the disc, (3) bone harvesting 30 usually from the patient's iliac crest, (4) bone cement filling of the donor site, (5) donor bone packing into the vacant disc space, (6) supporting adjacent vertebral bodies with rods, connectors, wire and screws, and finally (7) closing multiple surgical sites.

After a discectomy, numerous postoperative complications can occur. The major ones are lumbar scarring and vertebral instability. The scar tissue extends and encroaches upon the laminectomy site and intervertebral foramen, then once again, pain returns, which leads to more surgery. In fact, repeat operations are very common. Unfortunately, the success rates of repeat 5 operations are often less, in some cases, far less than the first. More operations lead to more scarring and more pain. Current recommendations to the patients are to avoid surgical procedures unless the pain and inconveniences are absolutely unbearable.

Even for the fortunate patients with long term success following discectomies performed twenty years ago, their isokinetic test results clearly indicate weaknesses compared to populations 10 without discectomies.

There was and still is increasing interest in more effective and less invasive surgical techniques on the spine to reduce both trauma and cost. The major objectives of surgery on bulging or herniated lumbar discs are (1) decompression of the involved nerve root or roots, and (2) preservation of bony spine, joints and ligaments.

15 Chymopapain is an enzyme used to digest away the nucleus pulposus, the viscous and gel-like substance in the central portion of the disc, which then creates space for the bulging part of the disc to pull back from the encroached nerve root. The needle for injecting the chymopapain is accurately guided to the mid-portion of the disc by a stereotaxic device. The overall success rate is documented as high as 76%. However, some patients are allergic to the treatment and die from 20 anaphylaxis. Some others suffer from serious neuralgic complications, including paraplegia, paresis, cerebral hemorrhage and transverse myelitis.

25 Percutaneous nucleotomy is an alternative method for removing nucleus pulposus without the allergic reaction of chymopapain; and it rarely causes epidural scarring. Similar to chymopapain injection, a needle followed by a tube-like instrument is guided and confirmed by anteroposterior and lateral fluoroscopy. The nucleus pulposus is then removed mechanically or by vacuum. As a result, a void is created within the disc and the bulging decreases, like the air being released from a worn out tire, with the hope that the bulging portion of the disc will recede and no longer encroach upon the adjacent nerve root. This type of procedure is often referred to as a decompression procedure. However, the success of the percutaneous nucleotomy depends on the 30 openness or clarity of the nucleus pulposus channels or outlets leading to the bulge. If the channels are closed, which often is the case, evacuation of the nucleus pulposus from the center of the

vertebral disc does not affect the bulge and does not provide any benefit to the patient after the percutaneous nucleotomy procedure.

With age, the intervertebral disc continues to lose its ability to retain water, resulting in diminished disc height and narrowed disc space. Disc space narrowing leads to spinal stenosis, 5 which can be painful when nerves are impinged, entrapped or distorted, by the flattened disc or vertebral bone. Depletion of nucleus pulposus from the percutaneous nucleotomy procedure can also cause disc flattening or thinning, leading to vertebral instability and/or spinal stenosis.

Recently, several devices (US Patent No. 5,800,550 to Sertich, 1998; US Patent No. 5,683,394 to Rinner, 1997; US Patent No. 5,423,817 to Lin, 1995; US Patent No. 5,026,373 to 10 Ray et. al., 1991) were designed to fortify the disc space between vertebrae. These types of devices are frequently referred to as spinal cages. Before inserting the device into the disc, the affected disc with portions of vertebral bone above and below the disc are cored out. Usually two holes are cored on each side of the disc for insertion of two spinal cages. Donor bone or bone growth 15 promoting substances are packed into the porous cages. As the vertebrae heal from the coring, new bone grows into and permanently secures the porous cages. The purpose of using spinal cages is to replace the disc and keep the vertebrae apart. However, these vertebrae are permanently fused to each other, without resilient cushion, rotation or mobility.

An improved version of a metallic spinal fusion implant (US patent 5,782,832 to Larsen and Shikhman, 1998) tries to provide both rotational and cushioning capabilities. This invention 20 resembles a disc prosthesis following a complete discectomy. Therefore, at the least, all the complications and postsurgical problems associated with a discectomy also apply when this device is used.

Patent application, PCT/US99/21138, WO 00/40159 by Yeung and Yeung, introduces some devices and methods for fastening herniated and/or bulging discs. The application covers a 25 resiliently bent fastener, screw, suture, staple and tack, with methods to fasten and hold in the bulging annulus.

Tendon or Ligament Repair

In many accidents or sports related injuries, tendons or ligaments rupture from bones. The traditional repair is to drill through the bone, then pass a suture through to attach the torn tendon 30 back to the bone. Some very strong bone anchors (US patent 5,851,219 to Goble et. al., 1998; and US patent 5,478,353 to Yoon, 1995) have been invented and used with sutures to reattach ruptured tissues. The anchor with its attached suture is inserted into a pre-drilled bone hole. The

suture usually comes with a needle for sewing and attaching the torn tissue back to bone. However, suture manipulation requires time, delicate skill from surgeons and surgical space within the patient, which necessitates large and/or multiple incisions with increased risk and recovery time.

5

Meniscal Repair

Recently, instead of delivering, manipulating and retrieving sutures to repair tissue in a very tight surgical site, delivery of tacks with barbs (US Patent No. 5,702,462 to Oberlander, 1997; US Patent No. 5,398,861 to Green, 1995; US Patent No. 5,059,206 to Winters, 1991; US Patent No. 4,895,148 to Bays et. al., 1990; US Patent No. 4,884,572 to Bays et. al., 1989), staples (US Patent 10 No. 5,643,319 to Green et. al., 1997) and fasteners (US Patent No. 5,843,084 to Hart et. al., 1998; US Patent No. 5,374,268 to Sander, 1994; US Patent No. 5,154,189 to Oberlander et. al., 1992) have been proposed to hold torn tissue through small openings. Unfortunately, very few, if any, of these tacks, staples and fasteners have the holding strength to meet the standard set by sutures.

During the insertion of these devices into tissues, the barbs carve their way into their final 15 holding positions. Unavoidably, the carving damages and weakens the tissue, thereby decreasing the holding strength of the freshly inserted devices. As tension is applied to the fastened tissue, it is not surprising that the barbs can lose their grip, slip and creep along the carved paths created during insertion, leaving gaps in the supposed closure sites. The creeping problem of fastening devices is particularly evident in slow healing tissues, such as menisci, some ligaments and tendons. 20 When gaps are present, the torn tissue does not reattach and heal, even with the passage of time.

Non-biodegradable fasteners often have the problem of device migration, which can be devastating, especially when the device migrates into nerves, joints or vessels, after numerous cycles of tissue remodeling.

In summary, currently most of the tacks and fasteners have one or more of the following 25 drawbacks: (1) weak holding strength, (2) creeping and leaving gaps in the repair site and (3) potential migration into sensitive tissues.

SUMMARY OF INVENTION

All current approaches have one thing in common: tissue removal. Vastly different from 30 the tissue removing procedures, the methods described in the following two sections use techniques and devices to fasten and restrain the bulging, flattened and/or herniated disc to alleviate irritation of the nerve.

For fastening a bulging, herniated or compressed disc, a compression device is used to compress and repair the bulge. The compression device is comprised of a rod-like body, a pivotal toggle, a toggle-retaining nut, a toggle deployment device, a disc restrainer and a restrainer nut. During installation, the compression device is inserted through the defective or dysfunctional disc,

5 using the deployed toggle to distally anchor the compression device. The disc restrainer and the restrainer nut are used to compress and hold back the bulging annulus from impinging upon adjacent nerves, for supporting the annular sidewall or for adding disc height by consolidating annular tissue. Any excess length of rod of the compression device is then removed.

Another disc fastening device, a tissue fastener, comprises of a rod-like body with two sets of protruding resilient anchors for clamping tissue together. The sets of resilient anchors have opposite clamping directions to counter grip and fasten tissues located at both ends of the tissue fastener. When the tissue fastener is deployed within a bulging disc, the sets of anchors are designed to counter grip or clamp against two tissues, compressing, holding and fastening the tissues together. In the case of the bulging annulus, the tissue fastener compresses, maintains and

10 pinches in the bulge of the annulus. To deliver the fastener, the resilient anchors are compressed or folded within a fastener deployment tube or needle with a plunger located behind the tissue fastener. The deployment tube is inserted through the bulge into the disc, reaching healthy annulus on the other side. The bulge is compressed to a non-impinging position by a disc compressor.

15 While the compression is held, the fastener deployment tube is withdrawn while the plunger remains stationary. As the restriction of the deployment tube is lifted, the resilient anchors at each end open, counter fastening, restricting and clamping the annular tissues between two ends of the tissue fastener. Since the anchors are deployed or opened within the compressed annulus, the previously bulging annulus is mechanically anchored, fastened and restrained by the tissue fastener, freeing the adjacent nerve from impingement.

20 Both the compression device and the fastener are designed to hold, maintain and restrict the bulging annulus. Especially when multiple devices are used, the restrictions fortify the annulus and stabilize the intervertebral disc to minimize pain. Furthermore, the restrictions can also pinch in the annulus, adding disc height and minimizing nerve irritation induced by compressed or flattened discs, a common cause of spinal stenosis.

25 The tissue fastener and the delivery devices can also be sized and configured to fasten torn tissues, such as tendons, ligaments, menisci, organs, skin and/or other structures or devices.

Although percutaneous nucleotomy is not a reliable procedure to alleviate low back pain, in some cases, withdrawing nucleus pulposus provides the much needed pain relief without significant risks. One embodiment of this invention implants a disc drain tube to drain the nucleus pulposus from the swollen disc into the abdominal cavity. The disc drain tube has inlet and outlet openings 5 sized to drain the nucleus pulposus when disc pressure is high. To further regulate disc pressure, a pressure-sensing device coupled with a nucleus pulposus discharge gate can be installed within the drain tube.

REFERENCE NUMBER

| | | |
|----|-----------------------------------|-----|
| 10 | Bulging Disc | 100 |
| | Nerve Retractor | 101 |
| | Impinged Nerve | 102 |
| | Trocar | 103 |
| | Dilator | 104 |
| 15 | Nut | 105 |
| | Washer | 106 |
| | Toggle | 107 |
| | Rod with Thread | 108 |
| | Toggle Deployment Tube | 109 |
| 20 | Compression Device | 110 |
| | Disc Restrainer | 111 |
| | Restrainer Nut | 112 |
| | Anchor | 113 |
| | Rod-like Tissue Fastener Body | 114 |
| 25 | Lumen of Fastener Deployment Tube | 115 |
| | Penetration Marker | 116 |
| | Plunger | 117 |
| | Disc Compressor | 118 |
| | Normal Functioning Disc | 119 |
| 30 | Tissue Fastener Delivery Device | 120 |
| | Plunger Holding Screw | 121 |
| | Trigger | 122 |

| | |
|-----------------------------------|-----|
| Handle | 123 |
| Disc Drain Tube | 124 |
| Inlet | 125 |
| Outlet | 126 |
| 5 Impingement-Free Nerve | 127 |
| Nucleus Pulpous | 128 |
| Pressure-Sensing Device Connector | 129 |
| Pressure-Sensing Device | 130 |
| Discharge Gate | 131 |
| 10 Spring | 132 |
| Pin | 133 |
| Hinge | 134 |
| Meniscus | 135 |
| Drain Delivery Device | 136 |
| 15 Humerus | 137 |
| Tendon | 138 |
| Torn Tissue | 139 |
| Bone Hole | 140 |
| Bolt | 141 |
| 20 Attachment Slot | 142 |
| Anchor Hole | 143 |
| Tissue Fastener | 144 |
| Tissue Fastener Deployment Tube | 145 |
| Tissue Manipulative Device | 146 |
| 25 Tissue Manipulative Element | 147 |
| Disc Gripping Element | 148 |
| Restrainer Opening | 149 |
| Ball | 150 |
| Ball Coupling | 151 |
| 30 Ball Joint | 152 |
| Orientation Line | 153 |
| Stem of Disc Restrainer | 154 |

| | |
|-------------------------|-----|
| Tube with Inside Thread | 155 |
| Disc Restrictor | 156 |
| Linker | 157 |
| Link Site | 158 |
| 5 Vertebral Body | 159 |

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 depicts a trocar 103 inserted through a bulging disc 100.

Figure 2 shows the insertion of a dilator 104 through the bulging disc 100.

10 Figure 3 indicates a compression device 110 with a toggle deployment tube 109.

Figure 4 shows the advancement or sliding of the toggle deployment tube 109 moving the toggle 107 from a delivery position to a deployed position.

Figure 5 depicts insertion of the toggle 107 and compression device 110 through the dilator 104.

15 Figure 6 indicates the deployment of the toggle 107 outside the vertebral disc by the advancement of the toggle deployment tube 109.

Figure 7 depicts the installation of a disc restrainer 111 and a restrainer nut 112 on the threaded rod 108 of the compression device 110.

Figure 8 shows the tightening of the restrainer nut 112 and the disc restrainer 111 to press 20 in the bulging disc.

Figure 9 depicts the result of cutting the excess threaded rod 108.

Figure 10 indicates a depression in a disc restrainer 111 for concealing the restrainer nut 112.

Figure 11 indicates a bolt 141 for tightening the disc restrainer 111 onto a tube 155 with 25 inside thread, connecting to the toggle 107 assembly.

Figure 12 shows a mid-longitudinal view of two vertebral bodies 159 sandwiching a flattened or compressed disc 100.

Figure 13 depicts a mid-longitudinal view of a thickened intervertebral disc 100, induced by the compression device 110, further separating the two vertebral bodies 159.

30 Figure 14 shows a pair of toggles 107 linked by a hinge 134.

Figure 15 depicts a toggle 107 pivoting around a pin 133.

Figure 16 shows a disc restrictor 156 equipped with two disc restrainers 111 individually bolted onto a tube 155 with inside thread.

Figure 17 indicates a compressed or bulging disc 100 being fastened, supported and/or thickened by two disc restrictors 156.

5 Figure 18 depicts a tissue fastener 144 with anchors 113 resiliently deployed to counter grip tissues in their preferred or biased positions.

Figure 19 shows the tissue fastener 144 inside a tissue fastener deployment tube 145 with the anchors 113 resiliently folded or compressed in their delivery or closed positions.

10 Figure 20 depicts the insertion into a bulging disc 100 with the folded tissue fastener 144 and a plunger 117 within the fastener deployment tube 145.

Figure 21 indicates the compression of the bulging disc 100 by a disc compressor 118.

Figure 22 shows the deployment of the tissue fastener 144 by withdrawing the fastener deployment tube 145 while the disc compressor 118 presses down on the bulge and the plunger 117 remains stationary.

15 Figure 23 depicts a fully deployed tissue fastener 144 with extended anchors 113 holding and maintaining the compressed position of the annulus 119.

Figure 24 shows a tissue fastener delivery device 120 for delivering a tissue fastener 144.

Figure 25 depicts the tissue fastener delivery device 120 following the deployment of the tissue fastener 144.

20 Figure 26 indicates a sharpened tissue fastener tube 145 for use as a needle for tissue puncturing.

Figure 27 shows a cross-section of the mid-longitudinal view of the attachment between the plunger 117 and the tissue fastener 144 through a linker 157 on the plunger 117 onto a link site 158 of the tissue fastener 144.

25 Figure 28 indicates a partially withdrawn tissue fastener deployment needle 145 deploying the distal anchors 113 of the fastener 144 into the bulging disc 100.

Figure 29 depicts the inward pulling of the distal bulging 100 wall by the plunger 117 connected to the tissue fastener 144.

Figure 30 shows compression of the proximal bulging 100 wall by the disc compressor 118.

30 Figure 31 indicates the complete deployment of the tissue fastener 144 by fully withdrawing the tissue fastener deployment needle 145 from the bulging disc 100.

Figure 32 depicts the tissue fastener 144 disconnected from the plunger, counter gripping both distal and proximal annular tissues, thereby holding in the bulging disc 100.

Figure 33 shows two tissue fasteners 144 holding, supporting, strengthening and/or thickening the sidewall of the bulging disc 100.

5 Figure 34 indicates a well supported and thickened intervertebral disc 100, maintained and supported by two compression devices 110 and a tissue fastener 144.

Figure 35 shows a tissue fastener 144 with a spring 132 for a tight and added elastic fastening.

10 Figure 36 depicts anchors 113 of a tissue fastener 144 restricted within an elliptical fastener deployment tube 145, equipped with a plunger 117.

Figure 37 shows a disc compressor 118 and a disc restrainer 111 containing a stem 154 with two attachment slots 142 fitted over the fastener deployment tube 145.

Figure 38 depicts the fastening of the disc restrainer 111 by the deployed anchors 113 of the tissue fastener 144 after the removal of the fastener deployment tube 145.

15 Figure 39 depicts a combination of a tissue fastener 144 with a disc restrainer 111 to repair a bulging disc.

Figure 40 indicates a combination of compression device 110 and a tissue fastener 144 to repair a bulging disc.

Figure 41 depicts a pair of wide anchors 113 for holding soft and fragile tissue.

20 Figure 42 indicates a pair of sharp anchors 113 for piercing and trapping tissue.

Figure 43 shows a pair of sharp and wide combination anchors 113 for penetrating then grasping and gripping tissue.

Figure 44 depicts a tissue fastener 144 with some deployed anchors 113 perpendicularly extended and closely packed to each other.

25 Figure 45 depicts a tissue fastener rod 114 with an anchor hole 143.

Figure 46 indicates a pair of modular anchors 113 fitted into the anchor hole 143.

Figure 47 shows an end view of a tissue fastener 144 with deployed anchors 113 aligned within the same plane.

30 Figure 48 depicts an end view of a tissue fastener 144 with deployed anchors 113 perpendicularly extended or oriented from each other.

Figure 49 indicates an end view of a tissue fastener 144 with deployed anchors 113 offset from each other.

Figure 50 shows a curved fastener deployment needle 145 with an orientation line 153 and penetration markers 116. A flexible tissue fastener 144 and plunger 117 are within the needle 145.

Figure 51 indicates a cross-section of a fastener 144 and a fastener deployment tube 145 with a widened lumen 115 to prevent fastener 144 rotation within the lumen 115.

5 Figure 52 depicts a mid-longitudinal view of a fastener rod 114 equipped with a ball joint 152, formed by a ball 150 connected to a ball coupling 151.

Figure 53 shows a disc drain tube 124 with nucleus pulposus inlets 125 and an outlet 126.

Figure 54 depicts the insertion of a disc drain tube 124 into a bulging disc 100.

10 Figure 55 indicates the draining of the nucleus pulposus 128 by the disc drain tube 124 resulting in a non-bulging disc 119.

Figure 56 shows a disc drain tube 124 with a nucleus pulposus pressure sensing device 130 and discharge gate 131.

Figure 57 depicts a compression device 110 with nucleus pulposus draining capability.

15 Figure 58 indicates the insertion of a tissue fastening deployment tube 145 with a tissue fastener 144 through a torn tendon 138 into a bone hole 140.

Figure 59 shows a tissue-manipulating device 146 positioning the torn tendon 138 back over the bone hole 140.

Figure 60 depicts a fully deployed tissue fastener 144 fastening the torn tendon 138 back onto the bone.

20 Figure 61 shows a tissue fastener 144 holding a torn 139 portion of a meniscus 135.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Low Back Pain

Low back pain from bulging, herniated or compressed discs 100 is one of the most 25 common, prevalent, costly, painful and debilitating ailments afflicting mankind. As mentioned, treatments ranging from traditional to percutaneous approaches all have their drawbacks; some are very serious.

All current approaches have one thing in common: tissue removal. Vastly different from the tissue removing procedures, the methods described in the following two sections use 30 techniques and devices to fasten and restrain the bulging, flattened and/or herniated disc 100 to alleviate irritation of the nerve 102.

Compression Device, Disc Restrictor and Methods for Restraining Bulging Discs

Placement of the compression device 110 begins with a trocar 103 guided through the bulge into the intervertebral disc 100, as depicted in Figure 1. A laminotomy, removal of a small portion of laminal bone, may be necessary to access the bulge. Numerous existing guiding 5 techniques, such as anteroposterior and lateral fluoroscopy, MRI, ultrasound or others can be used to guide the trocar 103 into place. To avoid injury of blood vessels, such as the common iliac artery or vein, located anterior to the intervertebral disc 100, an angiogram of the blood vessels can be mapped out prior to trocar 103 insertion. Following the trocar 103, a dilator 104 is inserted into the bulging disc 100, as shown in Figure 2. The trocar 103 is then removed.

10 Figure 3 depicts a compression device 110 with a threaded rod 108 as the body, a nut 105 and a washer 106 to hold a toggle 107, and a deployment tube 109 to activate the toggle 107. The unique tubular toggle 107 on the compression device 110 is designed to provide high tensile strength and conform within a small cylindrical space within the dilator 104. The toggle 107 has two semi-cylindrical sections centrally connected with openings facing opposite directions. In a 15 delivery position, the concave sides of the opposing semi-cylindrical sections partly cover the rod 108; as depicted in Figure 3, the toggle 107 aligns parallel and fits over the threaded rod 108 of the compression device 110. In a deployed position, the toggle 107 rotates or opens, forming a T-like configuration with the rod 108 of the compression device 110, as shown in Figure 4. In the delivery position, the compression device 110 is inserted into the dilator 104 as indicated in Figure 20 5. The toggle 107 is deployed outside the annulus by a gentle push of the sliding toggle deployment tube 109, as indicated in Figure 6, to secure the compression device 110 at the distal end. Both the deployment tube 109 and the dilator 104 are withdrawn from the bulging disc 100. A disc restrainer 111 and a restrainer nut 112 are installed on the threaded rod 108 as depicted in Figure 7.

25 To prevent possible movement of the compression device 110, especially on the weakened bulging annulus, disc gripping elements 148 on the disc restrainer 111, as shown in Figures 7 and 10, are designed to grasp, hold and/or bundle the weakened annulus together during compression of the bulging disc 100. The bulge is compressed by the disc restrainer 111 and the restrainer nut 112, away from the adjacent, previously impinged nerve, as depicted in Figure 8. The disc 30 restrainer 111 can be made of a resilient or elastic material, such as nickel-titanium alloy or tempered stainless steel spring, to snugly compress and conform to the contour of a normally shaped annulus with minimal protrusion.

Excess threaded rod 108 is cut by a pair of endoscopic pliers (not shown); the result is shown in Figure 9. Figure 10 shows a depression or a recessed pocket in a disc restrainer 111 for concealing the restrainer nut 112 to minimize the possibility of neural impingement by a protruding restrainer nut 112. It is also possible to eliminate the cutting of the threaded rod 108 by 5 substituting the restrainer nut 112 with a bolt 141. In Figure 11, the bolt 141 passes through a depression or a recessed pocket of the disc restrainer 111 into a tube 155 with inside thread, connected to the toggle 107 assembly. As the bolt 141 advances into the tube 155 and toggle 107 assembly, the disc restrainer 111 is tightened, restricted, compressed and fastened into the annulus.

In addition to alleviating nerve 102 impingement by repositioning the bulging annulus 100, 10 the compression and tightening of the bulging disc 100 by the restrainer 111 can collapse and seal channels of the leaking nucleus pulposus 128, thus stopping the herniation.

Back pain caused by a flattened, bulging or compressed disc 100 may lead to intervertebral instability or spinal stenosis. The intervertebral instability resembles an out-of-control car riding on one or more flat tires with deflated and unsupported sidewalls. A flattened intervertebral disc 100 15 causes swaying between vertebral bodies, leading to pain in surrounding ligaments and facet joints. Figure 12 shows a mid-longitudinal view of a flattened bulging disc 100 between two vertebral bodies 159. Figure 13 indicates the compression-induced support and thickening of the previously bulging disc 100 by the compression device 110. The compression fortifies and supports the sidewall of the annulus from rolling, thereby minimizing vertebral instability. The bulging and 20 flattened disc 100 is being compressed and consolidated, thereby adding cushioning annulus to build height between the two vertebrae 159. The main functions of the compression device 110 are to fasten, restrict, tighten, support, fortify, maintain and/or pinch in the annulus of a bulging or flattened disc 100 to alleviate nerve 102 impingement and minimize intervertebral instability and spinal stenosis.

25 Other forms of toggles 107 can also be used to fasten bulging or herniated intervertebral discs 100. A two-pieced toggle 107 linked by a hinge 134 connected by a pin is shown in Figure 14. Figure 15 depicts a pivotal toggle 107 rotating on another type of pin 133 or screw.

To improve the strength of disc fastening, two disc restrainers 111 can be individually tightened by two bolts 141 to restrict the bulging of an intervertebral disc 100. The modified 30 device is called a disc restrictor 156, as shown in Figure 16. To install the disc restrictor 156, it is likely that both abdominal and posterior incisions are required, followed by trocar 103 and dilator 104 insertions.

Figure 17 depicts two disc restrictors 156 fastening, tightening, restricting, supporting and/or pinching in four sections of annulus of a bulging disc 100, adding sidewall support to minimize intervertebral instability and/or building disc height to minimize spinal stenosis in four sections of the bulging and/or flattened disc 100. Similarly, multiple compression devices 110 can 5 also be guided and installed through posterior incisions to minimize back pain and repair dysfunctional intervertebral disc 100.

The compression device 110 or the disc restrictor 156 is well suited for fastening a lateral bulging annulus without excessively encroaching upon the anterior and posterior longitudinal ligaments and without protruding into the spinal canal. The angle of trocar 103 penetration is 10 directed posterior to the common iliac vessels or inferior vena cava. Surgical placement of the compression device 110 can also be done anteriorly through the abdomen to avoid injury to the blood vessels.

To further avoid blood vessels or vertebral bone, the trocar 103 and the dilator 104 can be made with curvatures. To accommodate the curvature of the dilator 104, the compression device 15 110 can be made with flexible material.

Components of the compression device 110 or the disc restrictor 156 can be made with material such as titanium, nickel-titanium, stainless steel or other metals or alloys. Some relatively new and biocompatible polymers, such as poly-ether-ether-ketone, DELRIN (acetal resin), polysulfone, polycarbonate, polypropylene, polyethylene or others, may have sufficient strength 20 and durability. Especially for testing purposes, a biodegradable compression device 110 or a portion of the device can be made with poly-lactate, poly-glycolic or other biodegradable polymers. All materials should be able to withstand sterilization by gamma, electron beam, ETO or steam to prevent infection.

The compression device 110 and the disc restrictor 156 can also be coated or blended with 25 radiopaque, echogenic, growth factor, analgesic, sealing, blood clotting, anti-biotic and/or other materials.

Unlike microdiscectomy or percutaneous nucleotomy, the compression device 110 and/or the disc restrictor 156 preserves disc material and provides direct, predictable and durable repair of the defective or dysfunctional disc 100 with the potential to stop further leakage of nucleus 30 pulposus. Disc fastening also provides the possibilities of minimizing intervertebral instability and increasing disc height to relieve pain and/or discomfort.

Tissue Fastening Devices and Methods for Fastening Bulging Discs

Another intervertebral disc fastening device called a tissue fastener 144 is designed to function while embedded entirely within the repaired disc 119. Three major benefits of using the tissue fastener 144 are (1) minimal possibility of rupturing major blood vessels since it does not 5 penetrate through the anterior side of the dysfunctional disc 100, (2) dissection of anterior and posterior longitudinal ligaments is not necessary and (3) no part protrudes to impinge nerve 102, spinal cord or blood vessels.

Figure 18 depicts a tissue fastener 144 with a rod 114 as body and resilient anchors 113 as tissue clamping elements in their deployed positions. The anchors 113 or clamping elements are 10 made with elastic or shape memory material, biased toward the open or deployed positions. The anchors 113, with distinct gripping directions, are designed to counter clamp, grip, fasten and hold tissues together, resisting pullout from the tissue. The rod 114 joins the anchors 113 and provides the tensile strength required to hold two tissues together. The resilient anchors 113 are designed to be elastically or resiliently folded or compressed within a fastener deployment tube 145, as 15 depicted in Figure 19, for delivery into a bulging disc 100. The folded spring-like anchors 113 are in delivery positions in the fastener deployment tube 145.

To install the tissue fastener 144, a trocar 103 is guided through the bulge 100 into the intervertebral disc with anteroposterior and lateral fluoroscopy, MRI, ultrasound or another method. Unlike Figure 1, the trocar is preferred not to penetrate through the intervertebral disc 20 100, thus avoiding the possibility of puncturing blood vessels. Following the trocar 103, a dilator 104 is inserted into the disc 100 to enlarge the opening.

The fastener deployment tube 145, loaded with a tissue fastener 144, is inserted into a bulging disc 100, as indicated in Figure 20. A disc compressor 118 or tissue manipulative device is used to press the bulge back to a non-nerve-impinging position, as depicted in Figure 21. While 25 the compressor 118 is pressing back the bulge and the plunger 117 is held stationary, the fastener deployment tube 145 is withdrawn to deploy the tissue fastener 144 within the compressed intervertebral disc, as shown in Figure 22. Since the resilient anchors 113 are made of elastic or shape memory material, when the restriction of the fastener deployment tube 145 is lifted, the resilient anchors 113 extend outward to their deployed positions. The anchors 113 at the distal 30 end of the tissue fastener 144 grip and fasten onto the healthy annulus. The anchors 113 at the proximal end of the fastener 144 open to clamp, grip, fasten and hold the compressed annulus in place. In essence, the deployed tissue fastener 144 locks and maintains the compressed, previously

bulging annulus in a non-nerve-impinging position, forming a repaired disc 119, as shown in Figure 23. At the same time, the compression and fastening of the bulging annulus can, and likely will, collapse and seal the channels of the leaky nucleus pulposus 128 near the bulging annulus, stopping the herniation.

5 For the surgeon's convenience, inserting the fastener deployment tube 145, compressing the bulging disc 100 and deploying the tissue fastener 144 can all be done with one hand. Figure 24 shows a tissue fastener delivery device 120 with a tissue fastener 144 in the lumen of fastener deployment tube 145 operated by a trigger 122, a stationary plunger 117 held by plunger screws 121 and a built-in disc compressor 118 attached to the device handle 123. A trigger lock can be
10 added to prevent the accidental release of the tissue fastener 144 during device 120 insertion. Figure 25 shows the deployment of the tissue fastener 144 from the tissue fastener delivery device 120 by using the trigger 122 to withdraw the fastener deployment tube 145. With the restriction of the deployment tube 145 removed, the anchors 113 of the tissue fastener 144 extend to their preferred deployed positions. It is also possible to load multiple tissue fasteners 144 within the
15 fastener deployment tube 145 with the capability of deploying one fastener 144 at a time, facilitated by increments in trigger 122 pulling. Multiple fasteners 144 can be used to anchor defective tissue, such as the intervertebral disc or others, in place. The distal end of the fastener deployment tube 145 can be sharpened, as indicated in Figure 26, to facilitate the puncturing of the bulging disc 100. The deployment tube or needle 145 can also be coated with radiopaque, echogenic, lubricant or
20 other coating material to facilitate device insertion.

For extra tight tissue fastening of the bulging disc 100, a linkage may be made between the plunger and the fastener 144 to provide pulling capability upon the annulus by the partially deployed fastener 144. Figure 27 depicts a mid-longitudinal view of a screw-like linker 157 protruding from the distal end of the plunger 117 and fastening into an inside threaded link site 158 in the tissue fastener 144. The linked assembly, located within a tissue fastener deployment needle 145, is then inserted into a bulging disc 100. Figure 28 indicates a mid-longitudinal view of deployed distal anchors 113 fastening onto the distal annulus of the bulging disc 100 by partially withdrawing the tissue fastener deployment needle 145, while holding the plunger 117 stationary. Figure 29 depicts the pulling of the plunger 117 connected to the tissue fastener 144, pulling in the
25 distal bulging annulus 100. Figure 30 shows the compression of the proximal bulging disc 100 by the disc compressor 118, while the plunger 117 is continuously being pulled. Figure 31 depicts the full deployment of the tissue fastener 144 by withdrawing the remaining portion of the tissue
30

fastener deployment needle 145 from the bulging disc 100, while continuing to compress the disc 100 and pull the plunger 117. After disconnecting the linker 157 of the plunger 117 from the link site 158 of the fastener 144, Figure 32 shows the fastener 144 tightly fastening the previously bulging disc 100 by counter gripping, clamping, holding, supporting and pulling in the annular wall 5 with the anchors 113.

Other connecting linkages between the tissue fastener 144 and the delivery device 120 are possible. For example, a screw from the proximal portion of the tissue fastener 144 can be inserted into a screw hole on the plunger 117. A latch or a hinge can couple with an indentation to link between the fastener 144 and the plunger 117, or between the fastener 144 and the tissue 10 deployment needle 145.

In addition to disc fastening using compression devices 110 in Figure 13 or disc restrictors 156 in Figure 17, other disc fastening devices, such as the tissue fasteners 144, can also minimize intervertebral instability and/or thicken intervertebral disc space to alleviate pain and discomfort. Figure 33 depicts the result of two counter gripping tissue fasteners 144 deployed by the method 15 described in Figures 27 to 32 to support, strengthen, restrict and/or pull in the annular wall of the bulging disc 100.

Figure 34 shows a previously flattened disc 100 repaired by the combination of two compression devices 110 and a tissue fastener 144 to build disc height in multiple sections of the disc 100 to treat spinal stenosis. At the same time, the flattened annulus is well supported to 20 minimize intervertebral instability. Figure 34 also indicates that the tissue fastener 144 can be well suited for fastening the mid-section of the compressed disc 100 by holding or restricting the anterior and posterior portions of the annular wall with no device protrusion in the central canal.

The tissue fastener 144 with an elastic spring 132, as indicated in Figure 35, is particularly well suited for restricting and strengthening the bulging disc 100. As the tissue fastener 25 deployment tube 145 is partially withdrawn, the distal anchors 113 extend out to make initial penetration into tissue. As the tissue fastener deployment tube 145 continues to be withdrawn, the deployment of the spring 132 follows. As the spring 132 is freed from the tubular 145 restriction, the spring 132 resiliently spreads apart in the gelatinous nucleus pulposus, pulling in the distal portion of the tissue fastener 144. The pulling of the fastener 144 facilitates the deployment of the 30 distal anchors 113, securing the clamping positions within the tissue, before the subsequent deployment of proximal anchors 113. It is also possible to link the spring 132 loaded fastener 144

to the plunger 117 for additional manipulation. In essence, the spring loaded tissue fastener 144 provides tight and elastic tissue fastening.

For holding and fastening degenerated or badly damaged annular tissue, the anchors 113 of the tissue fastener 144 can be utilized to fasten a disc restrainer 111. Figure 36 depicts anchors 5 113 of a tissue fastener 144 restricted in an elliptical fastener deployment tube 145 equipped with a plunger 117. A disc restrainer 111 having an elliptical opening 149 and a stem 154 with attachment slots 142 is fitted over the elliptical fastener deployment tube 145 along with a disc compressor 118, as shown in Figure 37. Alignment of the attachment slots 142 over the deployed anchors 113 is facilitated by the non-rotary elliptical stem 154 over the elliptical fastener 10 deployment tube 145. The assembly is inserted into the bulging disc 100. The disc compressor 118 is used to press the disc restrainer 111 against the bulge to a non-nerve-impinging position. While the disc compression continues and the plunger 117 is held stationary behind the tissue fastener 144, the elliptical fastener deployment tube 145 is withdrawn. As the restriction of the deployment tube 145 is removed, the resilient anchors 113 open and fasten into the adjacent 15 attachment slots 142 in the stem 154 of the restrainer 111, as indicated in Figure 38. The anchors 113 at the distal end of the tissue fastener 144 fasten onto healthy annulus, providing the fastening strength for the disc restrainer 111 to compress the bulging tissue.

It is also possible to have a combination of a tissue fastener 144 with a compression device 110 to repair a dysfunctional disc 100. Figure 39 depicts a bulging disc 100 repaired by resilient 20 anchors 113 at the distal end and a disc restrainer 111 with a restrainer nut 112 at the proximal end. This combination minimizes the possibility of injuring blood vessels anterior to the intervertebral disc and maximizes the restraint of a disintegrating bulging and/or herniated disc 100 posteriorly. The tissue fastener 144 and disc restrainer 111 combination can be made with a partially threaded rod 114 fitted within a tissue fastener deployment tube 145. After the anchors 25 113 are deployed by the withdrawal of the deployment tube 145, a disc restrainer 111 and a restrainer nut 112 are installed. Excess threaded rod 114 is cut; the result is shown in Figure 39. The disc restrainer 111 can also be connected to the tissue fastener 144 by anchors 113 as shown in Figures 37 and 38. The tissue fastener 144 can also link to the plunger 117 to provide pulling and manipulative capabilities to the fastener 144.

30 Figure 40 shows a bulging disc 100 repaired by a compression device 110 at the distal end and tissue fastener 144 at the proximal end of another combination device. This combination provides a strong toggle fastening combined with disc repair without protrusions near the nerve or

spinal cord. The combination is best suited for disc bulges 100 at or near the central canal. The concealed anchors 113 fasten and hold the previously bulging annulus 119 with minimal disturbances to the spinal cord and posterior longitudinal ligaments. The combination of compression device 110 and tissue fastener 144 can be achieved with a toggle deployment tube 109, which also serves as a tissue fastener deployment tube 145. A detachable linkage, similar to the one shown in Figure 27, may be used to connect the fastener 144 to the plunger 117 of a delivery device. The procedure for inserting and deploying the toggle 107 is similar to Figures 1, 2, 5 and 6. After the toggle 107 is deployed, the fastener-linked plunger 117 is pulled to secure the distal end of the combination device. A disc compressor 118 is then pressed into the bulging disc 100 and the toggle deployment tube 109 or the fastener deployment tube 145 is withdrawn to deploy the anchors 112. Similar procedures are shown in Figures 21 and 22. The linkage is then disconnected; and the result is a normal functioning disc 119, as shown in Figure 40, fastened by the combination devices.

One of the most important mechanisms in tissue anchoring by the fastener 144 is the initial tissue penetration. After withdrawing the tissue fastener deployment tube or needle 145, some anchor 113 penetration into the surrounding tissue during the anchor 113 deployment must be initiated. As the anchors 113 are pulled against the tissue, the anchors 113 flare open within the tissue, reaching the maximum anchoring power to firmly hook, clamp, trap and fasten the tissue. Therefore, the tip and/or the outer edge of the anchor 113 should have some tissue penetrating capabilities to initiate entry into the tissue, especially a tough tissue like the annulus. On the other hand, the inner edge of the anchor 113 is responsible for fastening, holding, clamping and trapping the tissue; therefore, it should be made as wide and as dull as possible to prevent cutting the tissue, thus maximizing the fastening strength of the tissue fastener 144.

The shape, stacking/orientation, spacing and numbers of the anchor 113 can influent the fastening strength of the tissue fastener 144. To maximize tissue-anchoring power, the shape of the anchors 113 on the tissue fastener 144 can make a significant difference. Figure 41 depicts a pair of wide anchors 113, which may provide effective anchoring in soft and easily ripped tissue, such as skin, lung, liver or other organs. Figure 42 shows a pair of sharp anchors 113, which may be good for anchoring tough, fairly dense and hard to rip tissue, such as bone or the annulus of intervertebral discs. The sharp anchors 113 open as a pair of hooks, catching and trapping the anchored tissue at the bases of the sharp anchors 113. Figure 43 indicates a pair of combination sharp and wide anchors 113. Within the tissue, the sharp tips can assist the wide anchors 113 to

initiate tissue penetration or a foothold, allowing the full deployment of the wide anchor 113 within the tissue. The combination may provide the maximum anchoring power without ripping tissue.

Additional anchors 113 may improve fastening strength of the tissue fastener 144. Figure 44 depicts the anchors 113 rotated between levels, allowing more anchors 113 to be densely stacked within a given length of the tissue fastener 144. As more anchors 113 are available, more layers of tissue will be fastened to further improve the fastening strength within a small space.

Many other factors, including the length, size, and resiliency of the anchors 113 and the rod-like body 114, also contribute to overall fastening strength and effectiveness of tissue fastening.

10 The composition of the tissue fastener 144 can be formed from modular parts. Figure 45 depicts an anchor hole 143 in the rod 114 of a tissue fastener 144. Figure 46 indicates a modular anchor 113 inserted into the anchor hole 143.

15 The alignment and/or the stacking of the anchors 113 can be customized, specifically for each type of tissue. The end view of the fastener 144 in Figure 18 is depicted in Figure 47, with the set of deployed anchors 113 aligned together to fasten onto tissue. This type of anchor 113 alignment is good for fastening thin tissue by minimizing the protrusion of the deployed anchors 113. Tissue fasteners 144 with anchors 113 aligned together, as indicated in Figure 47, may be ideal for repairing meniscal tears 139, as shown in Figure 61, since the meniscus 135 is a thin cartilage between delicate and sensitive femorotibial joint tissues. Figure 48 depicts the end view 20 of deployed anchors 113 similar to the ones in the fastener 144 shown in Figure 44. The anchors 113 are stacked over each other at right angles to hold large amounts and the most layers of surrounding tissue. This type of anchor 113 alignment, indicated in Figures 48 and 44, should provide the most anchoring power, which may be suitable for fastening a tendon 138 to bone. Figure 49 depicts the end view of a tissue fastener 114 with the top set of deployed anchors 113 25 slightly rotated from the set below, to provide some improved anchoring power over the one shown in Figure 47. This type of anchor 113 alignment may be useful for fastening bulging discs 100 without excessive protrusion towards the sensitive vertebral end plates, but at the same time occupying and anchoring the maximum amount of annulus to ensure a long lasting disc 100 repair.

30 The fastener deployment tube 145 can also be made with a curvature, as shown in Figure 50, to access a hard to reach bulge. To accommodate the curvature of the deployment tube 145, the rod 114 of the tissue fastener 144 and the plunger 117 should be made flexible or curved.

The orientation of the tissue fastener 144 may play an important role in the patient's comfort after the device has been implanted. It probably would not be comfortable to have the anchors 113 within the disc, pointing toward the end plates of both vertebral bodies 159 where pain sensation can be felt. To avoid such post-surgical discomfort, the tissue fastener 144 is loaded 5 and oriented so that the anchors 113 are aligned with a visible orientation line 153 drawn on the fastener deployment tube 145, as indicated in Figure 50. Similarly, the tissue fastener 144 can be loaded in a designated orientation with respect to the handle 123 of the delivery device 120. To ensure proper fastener 144 alignment relative to the orientation line 153 or the handle 123, the inside lumen 115 or chamber of the fastener deployment tube 145 can be widened or made non- 10 round to prevent or limit fastener 144 rotation within the tube 145, as depicted in a cross-sectional view in Figure 51. With the guidance of the orientation line 153 or the handle 123, the surgeon can avoid deploying the anchors 113 toward the direction of sensitive areas. Furthermore, to indicate the depth of device insertion, penetration markers 116 can be drawn on the fastener deployment tube 145, as shown in Figure 50, and also on the disc compressor 118, as an important 15 verifiable reference point to the surgeon.

It is possible to add a joint or link in the rod 114 to provide extra flexibility and rotation between two anchoring ends of the tissue fastener 144. Figure 52 depicts a mid-longitudinal view of a ball joint 152 between two sections of fastener rods 114 to allow rotation and flexibility. The ball 150 extends from one section of the rod 114 and is housed in a ball coupling 151 screwed onto 20 or formed in another section of the rod 114.

Since the guiding techniques for inserting the tissue fastener 144 into the bulging or herniated discs 100 are similar to the ones used in relatively low risk percutaneous nucleotomy procedures and routine diagnostic discography for determining herniations, the methods used in fastening bulging or herniated discs 100 should also be low in risk and complications. However, 25 the success of percutaneous nucleotomies depends on the condition of the nucleus pulposus channels leading to the bulge. If the channels are closed, which is often the case, evacuation of the nucleus pulposus within the center of the vertebral disc does not affect the bulge and provides no benefit to the patient after the percutaneous nucleotomy procedure. Unlike the indirect and open channel dependent percutaneous nucleotomy procedure, the tissue fastener 144 is a direct 30 mechanical device that hooks and locks the bulging annulus back into place. The results should be far more effective, predictable and longer lasting, with no higher risks or complications.

The tissue fastener 144 can be made with alloy, pure metal, polymer and/or composites. For super elastic and/or shape memory properties, nickel-titanium alloy can be used for the anchors 113 and/or the flexible rod 114. A stainless steel tempered spring may also provide adequate resiliency, flexibility and elasticity, with sufficient biocompatibility for making the anchors 113 5 and/or the entire tissue fastener 144. Many polymers, such as poly-sulfone, poly-ether-ether-ketone, DELRIN (acetal resin), polycarbonate, polyurethane, polypropylene, polyethylene and/or others, may have the physical and biological characteristics required to be a part of the tissue fastener 144.

Although the counter tissue gripping anchors 113 on the fastener 144 can, and mostly likely 10 will, resist device migration with time, after the tissue is adequately reattached or healed, it may be beneficial if a part or the entire tissue fastener 144 is biodegradable. Poly-lactate, poly-glycolate, collagen, elastin or other materials may provide the degradation profile to fasten then resorb after the tissue has reattached and healed.

To improve upon their performance, the tissue fastener 144 can be coated with radiopaque 15 material, echogenic material, growth factor, antibiotic, analgesic, sealant, lubricant, nutrient and/or other substances.

The benefits of intervertebral disc 100 fastening include: (1) alleviating nerve 102 20 impingement, (2) minimizing spinal stenosis and/or (3) stabilizing intervertebral disc 100. Annulus compression can be achieved with disc fastening devices, including the compression device 110, disc restrictor 156, tissue fastener 144 and any combinations of these devices.

Disc Draining Device and Method to Relieve Low Back Pain

Percutaneous nucleotomy is often used to relieve low back pain by evacuating the nucleus pulposus 128 to decompress the intervertebral disc 100. However, when the fluid builds up again in the future, low back pain returns.

25 Figure 53 depicts a disc drain tube 124 with nucleus pulposus inlets 125 and an outlet 126. The drain tube 124 is inserted into a swollen intervertebral disc 100 through a drain delivery device 136 equipped with a plunger 117, as shown in Figure 54. The construction of the drain delivery device 136 can be similar to the tissue fastener delivery device 120 in Figures 24-26. To aid with the insertion, penetration markers and/or curvature on the drain delivery device 136 can be helpful. 30 The plunger 117 is held stationary while the drain delivery device 136 is withdrawn to deposit the disc drain tube 124 within the swollen disc 100. Figure 55 depicts the uptake of the nucleus pulposus 128 drawn from the channels near the bulge of the disc 100 and the central reservoir

through multiple inlets 125, draining through the outlet 126 into the abdomen. As a result, the bulge 119 reduces in size, away from the previously impinged nerve 127, as shown in Figure 55. The drain tube 124 can also be inserted anteriorly through the abdominal cavity to lower the risk of rupturing blood vessels, facilitating proper placement of the outlet 126 and creating only one 5 incision.

Since the nucleus pulposus 128 is a viscoelastic gel with dynamic modulus ranging from 7 to 20 kPa, the pressure in the drained intervertebral disc 119 can be regulated or controlled by the diameter of the drain tube 124, number of inlets 125, sizes of the inlets 125 and/or the size of the outlet 126. If the number of inlets 125 is few and diameters of the tube 124, inlets 125 and outlet 10 126 are small, the disc pressure will remain high. On the other hand, if the inlets 125 are numerous and the diameters of the tube 124, inlets 125 and outlets 126 are large, allowing significant nucleus pulposus 128 drainage to pass, the disc pressure will be low.

To improve disc pressure regulation, a connector 129 mounting a pressure sensing device 130 coupled with a nucleus pulposus 128 discharge gate 131 can be installed with the disc drain 15 tube 124, as depicted in Figure 56. As the pressure begins to build up within the disc 100, the sensing device 130 triggers the gate 131 to open, allowing the nucleus pulposus 128 to escape out of the outlet 126 slits into the abdominal cavity. It is possible to build a disc drain tube 124 with a variety of pressure regulating designs to regulate and maintain the pressure within the intervertebral disc 119.

20 The inlets 125 depicted in Figures 53 and 56 are deep and sunken into the disc drain tube 124 for three major functions: (1) to provide adequate drainage mainly from the central portion of the disc, (2) to minimize the diameter of the tube 124 and (3) to provide tissue ingrowth and/or gripping in the annular portion of the disc, thus preventing tube 124 migration with time. Tissue gripping elements can also be added onto the outer surface of the tube 124 to prevent migration.

25 The drain delivery device 136 and the drain tube 124 can also be made curved to avoid blood vessels, bone or nerves to promote proper drainage by tapping into channels of herniating nucleus pulposus 128, using the drain tube 124 as a spigot to release the inflated bulge.

30 For various reasons, such as uncertain efficacy or degenerating discs, the disc drain tube 124 can be made biodegradable with poly-lactate, poly-glycolate, collagen, elastin or other degradable materials.

For long term pulposus 128 pressure regulation, metallic material, such as stainless steel, titanium or nickel-titanium, are suitable. Metallic material is preferred, especially if the distal end

of the disc drain tube 124 is sharpened for disc puncturing capability. Numerous long lasting polymers, such as poly-ether-ether-ketone, polysulfone, polycarbonate, PTFE, polyurethane, DELRIN (acetal resin), polypropylene, polyethylene or others may meet adequate physical and biocompatible requirements.

5 To improve upon its performance, the disc drain tube 124 can be coated with a radiopaque compound, echogenic compound, growth factor, antibiotic, analgesic, sealant, lubricant, nutrient or other substances.

10 Although the single evacuation of nucleus pulposus 128 by the percutaneous nucleotomy procedure is well accepted due to the low risk in treating herniated discs 100, the disc drain tube 124 provides a continually regulated and/or monitored drainage to prevent further swelling or herniation with a similar low risk level. The disc drain tube 124 may provide prolonged or even permanent relief for Types II to VI low back pain.

15 It is also possible to combine the benefits of the disc drain tube 124 with those of mechanical fastening using the compression device 110 for example, as indicated in Figure 57. The threaded rod 108 is made hollow with nucleus pulposus inlets 125 and an outlet 126, and sealed near the disc restrainer 111 end. The mechanical fastening of the compression device 110 provides instant pain relief by alleviating the impinged nerve 102, while the drainage reduces the swelling of the disc.

Tendon Repair With Tissue Fastener

20 Tendon 138 rupture from bone commonly occurs in sports injuries and other accidents. Bone anchors (prior art) are most frequently used with tedious and delicate suture manipulative techniques to reattach torn tendon 138 back onto bone. To eliminate the trouble of suture manipulation, the tissue fastener 144 can be used to fasten the torn tendon 138 directly back onto bone.

25 To reattach tendon 138 with a tissue fastener 144, a hole 140 is drilled or punctured into bone, then a tissue fastener deployment tube 145 with at least one tissue fastener 144 is inserted through the tendon 138 into the bone hole 140, as indicated in Figure 58. A tissue-manipulating device 146 equipped with tissue manipulating elements 147 is used to position the tendon 138 onto the bone, as shown in Figure 59. To deploy the tissue fastener 144, the tissue fastener deployment tube 145 is withdrawn while the plunger 117 and the tissue-manipulating device 146 are held stationary. As a result, the distal half of the tissue fastener 144 anchors in the bone hole 140 and the proximal half anchors in the tendon 138, as depicted in Figure 60. Within weeks, the tendon

138 can, and most likely will, permanently reattach back onto the bone. Therefore, as mentioned previously, a biodegradable tissue fastener 144 can reattach tissue without the threat of device migration in the distant future or the creation of a stress riser, which weakens the bone.

For soft bone, such as the humerus 137 in the shoulder, as indicated in Figure 58, the tissue fastener deployment tube 145 can be sharpened as a needle, as shown in Figure 26, to puncture the humerus 137 without drilling. To ensure proper depth of insertion, penetration markers can be drawn on the outer surface of the tissue fastener deployment tube 145 to assist in the procedure. Similar delivery devices like the ones shown in Figures 24 and 26 can be used to puncture and manipulate tissues, then deliver and deploy the tissue fastener 144 with one hand, all through a tiny incision without the nuisance of suture manipulation.

Meniscal Repair With Tissue Fastener

Currently, suture repair of meniscal tears frequently requires retraction of nerves and vessels, resulting in a long and painful recovery. Existing products, such as meniscal darts, screws and tacks, often creep and leave gaps in the supposed closure sites, not allowing the torn tissue to reattach and heal.

Both the tissue fastener 144 and the tissue fastener deployment needle 145 can be sized and configured to fasten and repair torn meniscus 135. The tissue fastener deployment needle 145, as shown in Figure 26, punctures the meniscal body with the guidance of an arthroscope, traversing the tear 139. Penetration markers on the needle 145 can be helpful to determine the depth of needle 145 insertion. A tissue manipulating device 146 similar to the one used to position torn tendons 138, as shown in Figure 59, can be utilized to approximate the torn tissue 139 back to the main body of the meniscus 135. To deploy the tissue fastener 144, the plunger 117 is held stationary while the fastener needle 145 is withdrawn from the meniscus 135. When the restriction of the fastener deployment needle 145 has been lifted, the anchors 113 resiliently open into deployed positions, gripping, holding, grasping, trapping, hooking and/or fastening tissues at opposing ends of the tissue fastener 144, as indicated in Figure 61. The anchors 113 from both ends of the fastener 144 have elastic gripping properties and are designed to resist pullout. As a result, the torn tissue 139 is elastically fastened and closed by the opposing grips of two sets of resilient anchors 113 of the tissue fastener 144, as shown in Figure 61.

In meniscal repairs, the fastener deployment needle 145 is effective for both outside-in and inside-out approaches. The outside-in approach is to enter from the thick peripheral rim of the meniscus 135 toward the thin tapered portion of the meniscus 135. The inside-out approach is to

enter from the thin portion toward the thick rim. The inside-out approach is more frequently used by surgeons using sutures or meniscal tacks because with tears occurring more often in the posterior portion of meniscus 135; it is less likely to disrupt vessels and nerves. The fasteners 144 and deployment needle 145 in this invention can accommodate both approaches.

5 Thin barbs on the meniscal tacks and darts, and the shallow thread of meniscal screws (prior art) can creep, leaving gaps under the enormous pressures exerted at the femorotibial joint. On the other hand, the long resilient and elastic anchors 113 of the tissue fastener provide continual spring-like closure forces rejoining the torn tissue 139, thereby allowing the meniscus 135 to heal and serve its function. If the fastener 144 is made with biodegradable material, the fastener 144
10 will eventually degrade.

Although meniscal suture repair is believed to be reliable, it often requires large incisions, multiple entry points, retractors to pull aside blood vessels, nerves and/or expansion of joint space for passing and manipulating suture. Each of these retractions involves risks, post-surgical complications, prolonged healing time and increased pain and medical costs. Conversely, the tissue
15 deployment needle 145 can deliver the spring-like tissue fastener 144 through a small incision for a quick recovery.

In brief summary, some of the possible benefits of the tissue fastener 144 and the delivery needle 145 are: (1) resilient tissue fastening, (2) minimal fastener migration, (3) minimally invasive, (4) accessible to deep body targets, (5) suture-free fastening, (6) attachable to bone, (7) minimal
20 surgical space, (8) permanent or degradable fastening, (9) simple to use and (10) capable of manipulating tissue.

It is also to be understood that the present invention is by no means limited to the particular constructions disclosed herein and/or shown in the drawings, but also comprises any other modification, changes or equivalents within the scope of the claims. Many features have been
25 listed with particular configurations, options, and embodiments. Any one or more of the features described may be added to or combined with any of the other embodiments or other standard devices to create alternate combinations and embodiments.

It should be clear to one skilled in the art that the current embodiments, materials, constructions, methods, tissues or surgical sites are not the only uses for which the invention may
30 be used. Different materials, constructions, methods or designs for the compression device 110, restricting device 156, tissue fastener 144, drain tube 124 or the delivery devices can be substituted and used. The use of this invention is also foreseen to compress, restrict, reattach or reconnect

organ, muscle, skin, ligament, bone or other tissue. Nothing in the preceding description should be taken to limit the scope of the present invention. The full scope of the invention is to be determined by the appended claims.

I claim:

- 1 1. A compression device for treating a bulging, herniated or compressed intervertebral disc, said compression device comprising:
 - 3 a rod having a first end and a second end,
 - 4 a toggle pivotally connected with said rod, said toggle having a delivery position and a
 - 5 deployed position,
 - 6 and a disc restraining member attachable to said second end of said rod.
- 1 2. The compression device of claim 1 wherein, when said toggle is in said deployed position, said toggle is generally perpendicular to said rod, and when said toggle is in said delivery position, said toggle is generally parallel to said rod.
- 1 3. The compression device of claim 1 wherein said toggle comprises:
 - 2 a first generally semi-cylindrical portion,
 - 3 and a second generally semi-cylindrical portion,
 - 4 wherein, in said deployed position, a first concave surface of said first generally semi-
 - 5 cylindrical portion faces generally towards a proximal end of said rod and a second
 - 6 concave surface of said second generally semi-cylindrical portion faces generally
 - 7 towards a distal end of said rod,
 - 8 and wherein, in said delivery position, said first and second concave surfaces partially enclose
 - 9 said rod.
- 1 4. The compression device of claim 3 wherein said first and second semi-cylindrical portions are each defined by two sidewalls running parallel to a longitudinal axis of said toggle.
- 1 5. The compression device of claim 4 wherein said first semi-cylindrical portion connects to said second semi-cylindrical portion at a connecting portion including a first end surface of said first semi-cylindrical portion and a second end surface of said second semi-cylindrical portion.
- 1 6. The compression device of claim 5 wherein said first and second end surfaces form a non-ninety degree angle with said longitudinal axis.

1 7. The compression device of claim 3 wherein said first and second semi-cylindrical portions each
2 form more than a semi-circle in cross-section.

1 8. The compression device of claim 1 further comprising a nut attached to said first end of said
2 rod.

1 9. The compression device of claim 8 wherein said nut is larger than an opening passing through
2 said toggle.

1 10. The compression device of claim 1 wherein said toggle is connected with said first end of said
2 rod.

1 11. The compression device of claim 1 wherein said toggle is connected with said first end of said
2 rod by a pin.

1 12. The compression device of claim 11 wherein said toggle has a first member forming a first
2 portion and a second member forming a second portion of said toggle.

1 13. The compression device of claim 12 wherein said first and second members move
2 independently.

1 14. The compression device of claim 11 wherein said pin connects said toggle to said rod at a mid-
2 portion of said toggle.

1 15. The compression device of claim 1 wherein said disc restraining member has a plurality of
2 tissue gripping elements extending therefrom.

1 16. The compression device of claim 1 wherein said disc restraining member is resilient.

1 17. The compression device of claim 1 wherein said rod is threaded.

1 18. The compression device of claim 17 further comprising a nut holding said disc restraining
2 member.

- 1 19. The compression device of claim 18 wherein said disc restraining member has a depression and
2 said nut is at least partially recessed into said depression.
- 1 20. The compression device of claim 17 wherein said disc restraining member is located around a
2 threaded tubular member sized and configured to mate with said rod.
- 1 21. The compression device of claim 20 wherein said tubular member has an internally threaded
2 cavity and said cavity sized and configured to engage said rod.
- 1 22. The compression device of claim 21 wherein said tubular member is a hollow bolt.
- 1 23. The compression device of claim 17 wherein said rod has an internally threaded cavity
2 extending therein and said disc restraining member is located around an externally threaded bolt,
3 said bolt sized and configured to engage said cavity.
- 1 24. The compression device of claim 1 wherein at least a portion of said compression device is
2 formed of a material chosen from the group of materials consisting of titanium, nickel-titanium,
3 stainless steel, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate, polypropylene,
4 polyethylene, poly-lactate polymer and poly-glycolic polymer.
- 1 25. The compression device of claim 1 wherein said compression device is coated with a coating
2 chosen from the group of coatings consisting of radiopaque material, echogenic material, growth
3 factor, analgesic material, sealing material, blood clotting and antibiotic material.
- 1 26. The compression device of claim 1 wherein said compression device is flexible.
- 1 27. The compression device of claim 1 wherein said compression device is sized and configured to
2 treat a dysfunctional intervertebral disc.
- 1 28. A method for treating a bulging, herniated or compressed intervertebral disc, the method
2 comprising the steps of:
3 (a) inserting a rod of a compression device through the intervertebral disc;

4 (b) pivoting a toggle on a first end of said rod from a deployed
5 position;
6 (c) and connecting a disc restraining member with a second end of said rod.

1 29. The method of claim 28 wherein said rod is inserted such that said first end of said rod extends
2 outside the intervertebral disc.

1 30. The method of claim 28 further comprising the step of:
2 (d) manipulating a portion of the intervertebral disc with a tissue manipulation device.

1 31. The method of claim 28 further comprising the step of:
2 (d) manipulating a portion of the intervertebral disc with said compression device.

1 32. The method of claim 28 wherein step (a) is performed by inserting a tubular member
2 containing said compression device through the intervertebral disc.

1 33. The method of claim 28 further comprising the steps of:
2 (d) guiding a trocar into the bulging or herniated disc;
3 (e) inserting a dilator into the disc around said trocar;
4 (f) removing said trocar;
5 (g) and removing said dilator;
6 wherein steps (d) through (f) are performed prior to steps (a).

1 34. The method of claim 28 wherein said compression device is sized and configured to treat a
2 bulging intervertebral disc.

1 35. The method of claim 28 wherein said compression device is sized and configured to treat a
2 herniated intervertebral disc.

1 36. The method of claim 28 wherein said compression device is sized and configured to treat a
2 compressed or flattened intervertebral disc.

1 37. A compression device for treating a bulging, herniated or compressed intervertebral disc, said
2 compression device comprising:

3 a rod having a first end and a second end,

4 a first disc restraining member attachable to said first end of said rod,

5 and a second disc restraining member attachable to said second end of said rod.

1 38. The compression device of claim 37 further comprising a first threaded projection extending
2 from said first disc restraining member and a second threaded projection extending from said
3 second disc restraining member and wherein said rod is a tubular member having an passage
4 therein, the wall of said passage being internally threaded to mate with said first and second
5 threaded projections.

1 39. The compression device of claim 37 wherein said compression device is sized and configured
2 to treat a dysfunctional intervertebral disc.

1 40. A method for treating a bulging, herniated or compressed intervertebral disc, the method
2 comprising the steps of:

3 (a) inserting a rod of a compression device through the intervertebral disc, such that a first
4 end of said rod extends outside the intervertebral disc;

5 (b) connecting a first disc restraining member with said first end of said rod;

6 (c) and connecting a second disc restraining member with a second end of said rod.

1 41. The method of claim 40 further comprising the steps of:

2 (d) inserting a rod of a second compression device through the intervertebral disc, such that
3 a first end of said rod of said second compression device extends outside the
4 intervertebral disc;

5 (e) connecting a third disc restraining member with said first end of said rod of said second
6 compression device;

7 (f) and connecting a fourth disc restraining member with a second end of said rod of said
8 second compression device.

1 42. A tissue fastening device, comprising:

2 a rod having a first end portion and a second end portion,

3 a first tissue clamping element extending from said first end portion, said first tissue clamping
4 element formed of a resilient material, said first tissue clamping element having a
5 delivery position and a deployed position,
6 and a projection extending from said second end portion of said rod,
7 wherein, when said first tissue clamping element is in said delivery position, said first tissue
8 clamping element is located proximate to said rod,
9 wherein, when said first tissue clamping element is in said deployed position, said first tissue
10 clamping element extends outward from said rod,
11 and wherein said tissue fastening device compresses tissue between said first tissue clamping
12 element and said projection, thereby fastening the tissue together.

1 43. The tissue fastening device of claim 42 wherein said resilient material biases said first tissue
2 clamping element toward said deployed position.

1 44. The tissue fastening device of claim 42 wherein said projection is a toggle member connected
2 with said second end portion.

1 45. The tissue fastening device of claim 42 wherein said projection is a disc restrainer attachable to
2 said second end portion.

1 46. The tissue fastening device of claim 42 wherein said rod forms a drain tube to allow nucleus
2 pulposus from the disc to drain therethrough.

1 47. A tissue fastening device, comprising:
2 a rod having a first end portion and a second end portion,
3 a first tissue clamping element extending from said first end portion,
4 a second tissue clamping element extending from said first end portion, wherein said second
5 tissue clamping element extends generally opposite to said first tissue clamping element,
6 each of said tissue clamping elements being formed of a resilient material and having a
7 delivery position and a deployed position,
8 and a projection extending from said second end portion of said rod,
9 wherein, when said tissue clamping elements are in said delivery position, said tissue
10 clamping elements are located proximate to said rod,

11 wherein, when said tissue clamping elements are in said deployed position, said tissue
12 clamping elements extend outward from said rod,
13 and wherein said tissue fastening device compresses tissue between said tissue clamping
14 elements and said projection, thereby fastening the tissue together.

1 48. The tissue fastening device of claim 47 wherein, when in said delivery position, said first and
2 second tissue clamping elements extend toward said second end portion.

1 49. The tissue fastening device of claim 47 wherein said first and second tissue clamping elements
2 are spikes.

1 50. The tissue fastening device of claim 49 wherein said tissue fastening device is sized and
2 configured to treat a dysfunctional intervertebral disc.

1 51. The tissue fastening device of claim 47 wherein said first and second tissue clamping elements
2 are blunt.

1 52. The tissue fastening device of claim 47 wherein said first and second tissue clamping elements
2 are paddle-shaped.

1 53. The tissue fastening device of claim 47 wherein said tissue clamping element is generally
2 paddle shaped with a spike extending from an end thereof.

1 54. The tissue fastening device of claim 47 wherein said projection comprises:
2 a third tissue clamping element extending from said second end portion,
3 and further comprising a fourth tissue clamping element extending from said second end
4 portion, wherein said fourth tissue clamping element extends generally opposite to said
5 third clamping element.

1 55. The tissue fastening device of claim 54 wherein said third and fourth tissue clamping elements
2 are displaced along a longitudinal axis of said rod from said first and second clamping elements.

- 1 56. The tissue fastening device of claim 54 wherein, when said tissue fastening device is in said
- 2 delivery position, said third and fourth tissue clamping elements extend toward said first end portion
- 1 57. The tissue fastening device of claim 47 further comprising:
 - 2 a third tissue clamping element extending from said first end portion,
 - 3 and a fourth tissue clamping element extending from said first end portion, wherein said
 - 4 fourth tissue clamping element extends generally opposite to said third clamping
 - 5 element.
- 1 58. The tissue fastening device of claim 57 wherein said projection is a fifth tissue clamping
- 2 element extending from said second end portion, and further comprising:
 - 3 a sixth tissue clamping element extending from said second end portion, wherein said sixth
 - 4 tissue clamping element extends generally opposite to said fifth clamping element,
 - 5 a seventh tissue clamping element extending from said second end portion,
 - 6 and a eighth tissue clamping element extending from said second end portion, wherein said
 - 7 eighth tissue clamping element extends generally opposite to said seventh tissue
 - 8 clamping element,
 - 9 wherein said seventh and eighth tissue clamping elements are displaced along a longitudinal
 - 10 axis of said rod from said fifth and sixth clamping elements.
- 1 59. The tissue fastening device of claim 57 wherein said third and fourth tissue clamping elements
- 2 are offset from and generally perpendicular to said first and second tissue clamping elements.
- 1 60. The tissue fastening device of claim 57 wherein said third and fourth tissue clamping elements
- 2 are at a non-zero angle to said first and second tissue clamping elements.
- 1 61. The tissue fastening device of claim 47 wherein at least a portion of said tissue fastening
- 2 device is a nickel-titanium alloy.
- 1 62. The tissue fastening device of claim 61 wherein said nickel-titanium alloy has super elastic
- 2 properties.

1 63. The tissue fastening device of claim 61 wherein said nickel-titanium alloy has shape memory
2 properties.

1 64. The tissue fastening device of claim 47 wherein at least a portion of said tissue fastening
2 device is biodegradable.

1 65. The tissue fastening device of claim 47 wherein at least a portion of said tissue fastening
2 device is formed from a biodegradable material chosen from the group of biodegradable materials
3 consisting of poly-lactate polymer, poly-glycolate polymer, collagen and elastin.

1 66. The tissue fastening device of claim 47 wherein at least a portion of said tissue fastening
2 device is coated with a coating chosen from the group of coatings consisting of radiopaque
3 material, echogenic material, growth factor, antibiotic material, analgesic material, sealant,
4 lubricant and nutrients.

1 67. The tissue fastening device of claim 47 wherein at least a portion of said tissue fastening
2 device is formed from a polymer chosen from the group of polymers consisting of poly-sulfone,
3 poly-ether-ether-ketone, acetal resin, poly-carbonate, polyurethane, polypropylene and
4 polyethylene.

1 68. The tissue fastening device of claim 47 wherein at least a portion of said tissue fastening
2 device is metal.

1 69. The tissue fastening device of claim 47 wherein said projection is a toggle member connected
2 with said second end portion.

1 70. The tissue fastening device of claim 47 wherein said projection is a disc restrainer attachable to
2 said second end portion.

1 71. The tissue fastening device of claim 47 wherein said rod forms a drain tube to allow nucleus
2 pulposus from the disc to drain therethrough.

1 72. The tissue fastening device of claim 47 further comprising a linking means for linking said
2 tissue fastening device to a delivery device.

1 73. The tissue fastening device of claim 72 wherein said linking means is an opening extending
2 into said rod from an end surface thereof.

1 74. The tissue fastening device of claim 73 wherein said opening is threaded.

1 75. The tissue fastening device of claim 47 further comprising a joint in said rod located between
2 said first end portion and said second end portion.

1 76. The tissue fastening device of claim 47 further comprising a spring connecting said first end
2 portion to said second end portion of said rod.

1 77. The tissue fastening device of claim 47 wherein said tissue fastening device is formed from
2 modular components.

1 78. The tissue fastening device of claim 47 wherein said tissue fastening device is sized and
2 configured to treat a dysfunctional intervertebral disc.

1 79. The tissue fastening device of claim 47 wherein said projection is a first anchor element
2 extending from said rod and further comprising a second anchor element extending from said rod,
3 said anchor elements sized and configured to attach to a disc restraining member.

1 80. The tissue fastening device of claim 79 wherein said anchor elements engage attachment slots
2 in said disc restraining member.

1 81. The tissue fastening device of claim 80 wherein said anchor elements have a delivery position
2 in which said anchor elements are proximate said rod and a deployed position in which said anchor
3 elements extend outward from said rod and through said attachment slots.

1 82. The tissue fastening device of claim 79 wherein said anchor elements are formed of a resilient
2 material.

- 1 83. The tissue fastening device of claim 47 further comprising a delivery device for delivering the
2 tissue fastening device, said delivery device comprising:
 - 3 a tubular member having an internal chamber sized and configured to hold at least one of said
4 tissue fastening devices in said delivery position,
5 and a plunger located at least partially within said tubular member.

- 1 84. The delivery device of claim 83 further comprising a handle connected with said tubular
2 member and a trigger controlling said tubular member.

- 1 85. The delivery device of claim 83 wherein said tubular member has a sharpened tip.

- 1 86. The delivery device of claim 83 wherein said tubular member is curved.

- 1 87. The delivery device of claim 83 further comprising a plurality of penetration markers located
2 on said tubular member.

- 1 88. The delivery device of claim 83 further comprising an orientation line located along a
2 longitudinal axis of said tubular member.

- 1 89. The delivery device of claim 83 further comprising a tissue manipulation device located
2 proximate said tubular member.

- 1 90. The delivery device of claim 83 further comprising a tissue manipulation tube located at least
2 partially around said tubular member.

- 1 91. The delivery device of claim 83 further comprising a linking means connecting said plunger to
2 said tissue fastening device.

- 1 92. The delivery device of claim 91 wherein said linking means is a linking opening in said tissue
2 fastening device and a corresponding linking projection extending from said plunger.

- 1 93. The delivery device of claim 92 wherein said linking projection is externally threaded and said
2 linking opening is internally threaded, said linking projection being sized and configured to engage
3 said linking opening in an end surface of said tissue fastening device.
- 1 94. The delivery device of claim 83 wherein said internal chamber is non-round.
- 1 95. A method of fastening tissue using the tissue fastening device of claim 47, the method
2 comprising the steps of:
 - 3 (a) inserting a tubular member containing said tissue fastening device through the tissue to
4 be fastened;
 - 5 (b) and deploying said tissue fastening device by holding a plunger steady while
6 withdrawing said tubular member.
- 1 96. The method of claim 95 further comprising the step of:
 - 2 (c) manipulating the tissue with a tissue manipulation device.
- 1 97. The method of claim 95 further comprising the step of:
 - 2 (c) compressing the tissue with a tissue manipulation device.
- 1 98. The method of claim 95 wherein step (a) inserts said tubular member into an intervertebral
2 disc.
- 1 99. The method of claim 95 wherein step (a) inserts said tubular member into a tendon.
- 1 100. The method of claim 95 wherein step (a) inserts said tubular member into a ligament.
- 1 101. The method of claim 95 wherein step (a) inserts said tubular member into a meniscus.
- 1 102. The method of claim 95 further comprising the step of:
 - 2 (c) inserting said tubular member in a second location;
 - 3 (d) and deploying a second tissue fastening device in said second location.

1 103. The method of claim 102 wherein said second tissue fastening device is deployed at a non-
2 zero angle to the first tissue fastening device.

1 104. The method of claim 95 wherein said tissue fastening device is releasably attached to said
2 plunger and further comprising the steps of:

- 3 (c) partially deploying said tissue fastening device;
- 4 (d) pulling on said plunger to cause said tissue fastening device to compress tissue;
- 5 (e) completing deployment of said tissue fastening device;
- 6 (f) and disengaging said plunger from said tissue fastening device.

1 105. The method of claim 104 wherein step (f) is accomplished by rotating said plunger.

1 106. The method of claim 104 further comprising the step of:

- 2 (g) manipulating a portion of the tissue with a tissue manipulation device.

1 107. The method of claim 104 further comprising the step of:

- 2 (g) compressing the tissue with a tissue manipulation device.

1 108. The method of claim 95 wherein the tissue is an intervertebral disc and further comprising the
2 step of:

- 3 (c) compressing the intervertebral disc with a tissue manipulation device.

1 109. The method of claim 108 wherein said tissue fastening device is deployed to treat a
2 compressed or flattened intervertebral disc.

1 110. The method of claim 108 wherein said tissue fastening device is deployed to treat a bulging
2 intervertebral disc.

1 111. The method of claim 108 wherein said tissue fastening device is deployed to treat a herniated
2 intervertebral disc.

1 112. A method for treating a bulging, herniated or compressed intervertebral disc, the method
2 comprising the steps of:

3. (a) inserting a first compression device through the intervertebral disc, such that said first
4. compression device compresses the intervertebral disc along a first axis;
5. (b) and inserting a second compression device through the intervertebral disc, such that said
6. second compression device compresses the intervertebral disc along a second axis.

1 113. The method of claim 112 wherein said second compression device is deployed such that said
2 second axis is at a non-zero angle to said first axis.

1 114. The method of claim 112 further comprising the steps of:
2 (c) inserting a tissue fastening device into the intervertebral disc, such that said tissue
3 fastening device compresses the intervertebral disc along a third axis.

1 115. The method of claim 114 wherein said first and second compression devices and said tissue
2 fastening device are deployed such that said first, second and third axes are at non-zero angles to
3 one another.

1 116. A drain tube to treat an intervertebral disc for a bulge or herniation, the drain tube
2 comprising:
3 a hollow tubular member having an interior chamber, a wall, a first portion and a second
4 portion,
5 a plurality of holes passing through said wall in said first portion, said holes forming inlets
6 into said interior chamber,
7 and an outlet opening extending out of said interior chamber from said second portion.
8 wherein said drain tube is sized and configured to treat a bulging or herniated intervertebral disc.

1 117. The drain tube of claim 116 further comprising a discharge gate having an open position and
2 a closed position, wherein in said closed position, said discharge gate occludes said outlet opening.

1 118. The drain tube of claim 117 further comprising a pressure sensing device controlling said
2 discharge gate.

- 1 119. The drain tube of claim 116 wherein a size and a configuration of said plurality of holes is
2 chosen to maintain a selected range of pressure of nucleus pulposus outside said first portion of
3 said hollow tubular member.

- 1 120. The drain tube of claim 116 wherein at least one of a diameter of said interior chamber and a
2 size of said outlet opening is selected to maintain a selected range of pressure outside said first
3 portion of said hollow tubular member.

- 1 121. The drain tube of claim 116 wherein said first portion includes an end of said hollow tubular
2 member.

- 1 122. The drain tube of claim 116 further comprising a toggle member located proximate said
2 second portion of said hollow tubular member.

- 1 123. The drain tube of claim 122 wherein said first portion is a middle portion of said hollow
2 tubular member.

- 1 124. The drain tube of claim 123 wherein said hollow tubular member has a sealed first end and
2 further comprising a disc restraining member attached to said first end.

- 1 125. The drain tube of claim 116 wherein said drain tube is formed from a biodegradable material.

- 1 126. A method of draining nucleus pulposus from an intervertebral disc, the method comprising
2 the steps of:
 - 3 (a) inserting a first portion of a drain tube into the intervertebral disc;
 - 4 (b) allowing the nucleus pulposus to flow into said drain tube through inlet openings
5 extending through a wall of said first portion of said drain tube;
 - 6 (c) allowing the nucleus pulposus to flow out of said drain tube through an outlet opening
7 in a second portion of said drain tube.

- 1 127. The method of claim 126 further comprising the step of:
 - 2 (d) controlling the pressure within the intervertebral disc.

- 1 128. The method of claim 127 wherein step (d) is performed by a pressure sensing discharge gate.
- 1 129. The method of claim 126 further comprising the steps of:
 - 2 (d) allowing the nucleus pulposus to flow out of said outlet opening into an abdominal
 - 3 cavity of a patient.
- 1 130. The method of claim 126 wherein step (a) is performed by:
 - 2 (d) inserting a tubular member containing said drain tube into the intervertebral disc,
 - 3 (e) and holding a plunger located at least partially within said tubular member steady while
 - 4 withdrawing said tubular member.
- 1 131. The method of claim 126 wherein said drain tube is inserted to treat a bulging or herniated
- 2 intervertebral disc.

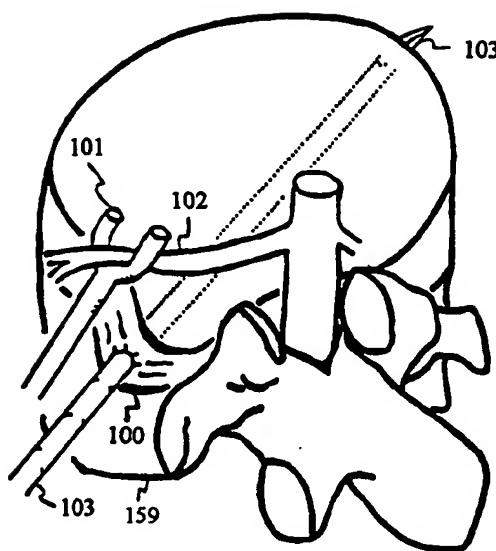


Figure 1

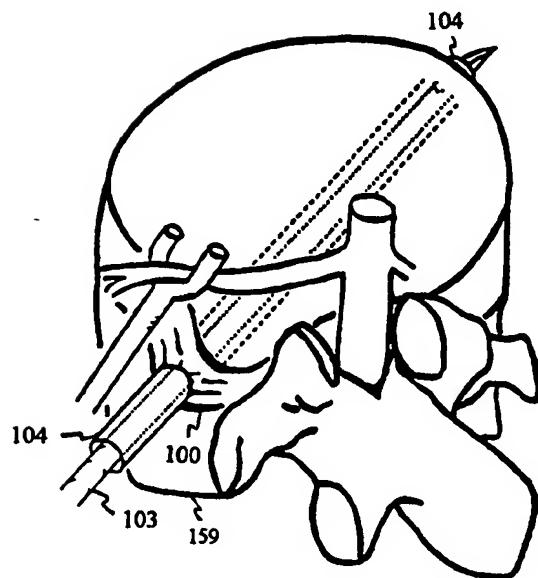


Figure 2

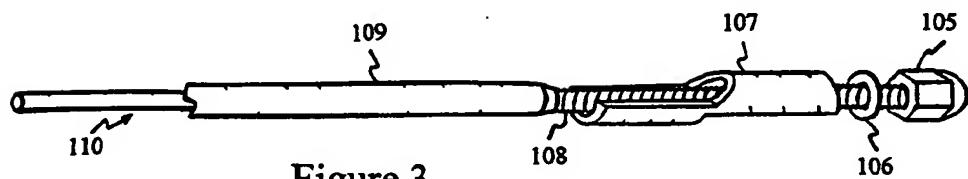


Figure 3

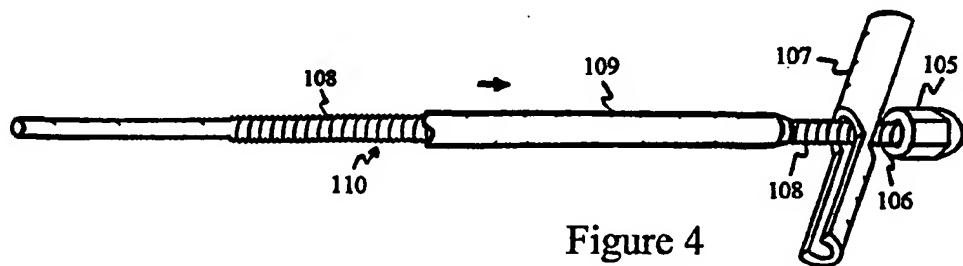


Figure 4

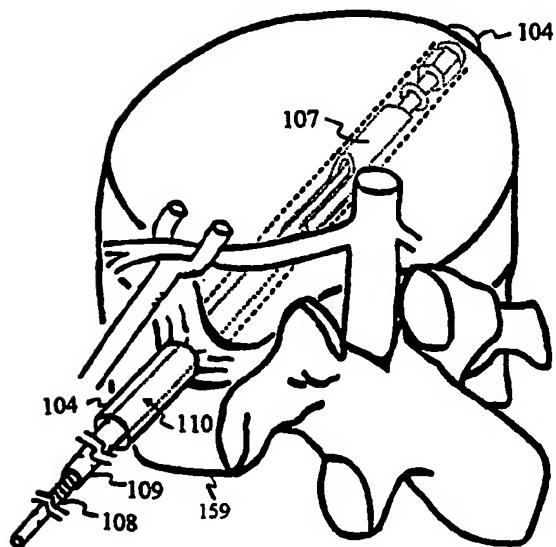


Figure 5

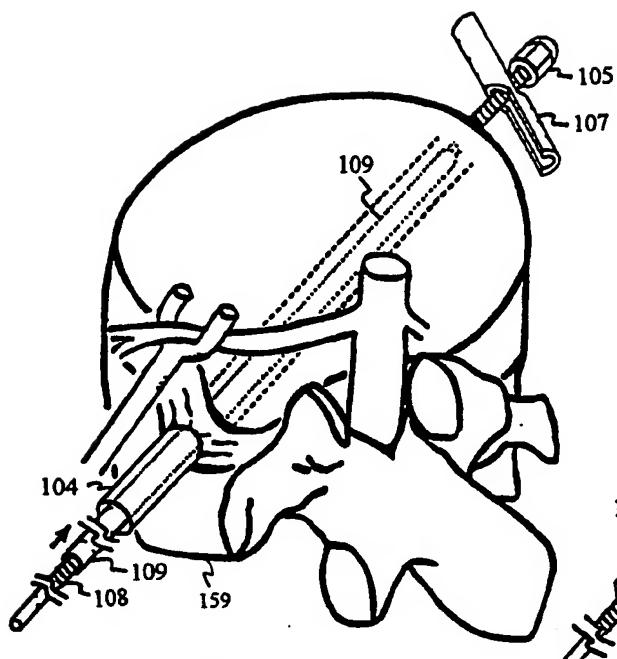


Figure 6

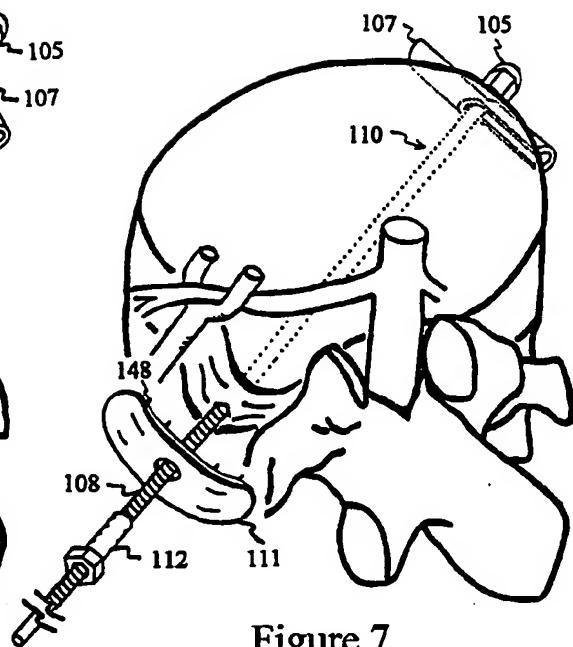


Figure 7

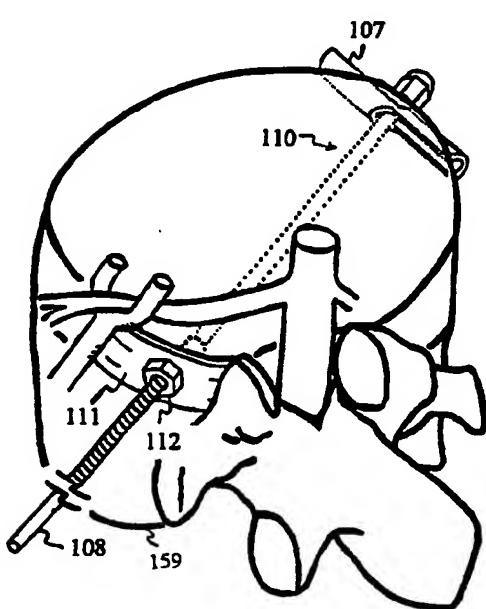


Figure 8

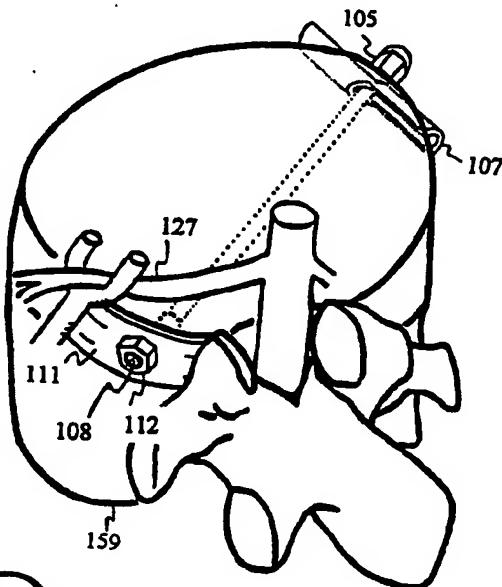


Figure 9

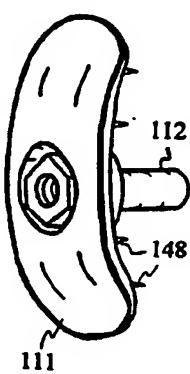


Figure 10

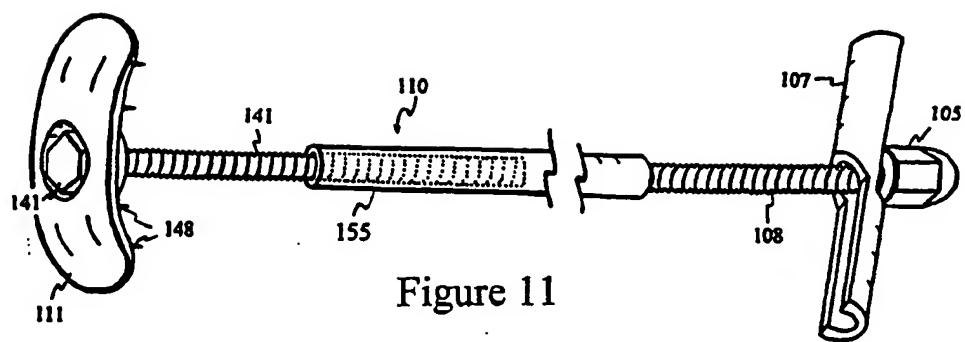


Figure 11

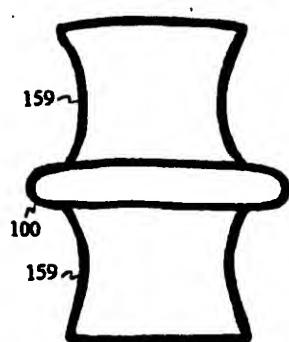


Figure 12

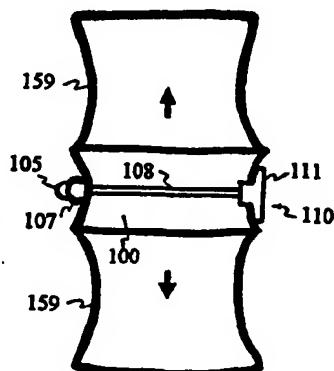


Figure 13

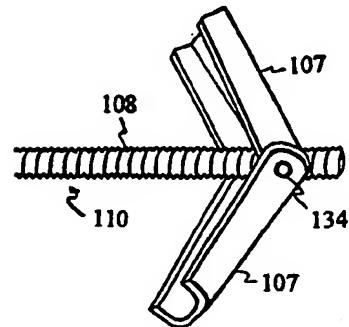


Figure 14

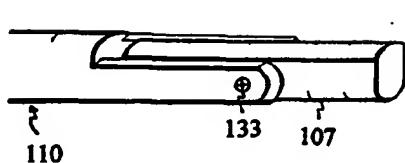


Figure 15



Figure 16

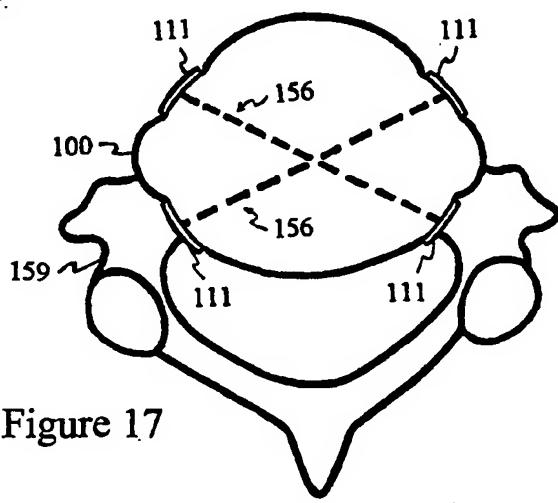


Figure 17

Figure 18

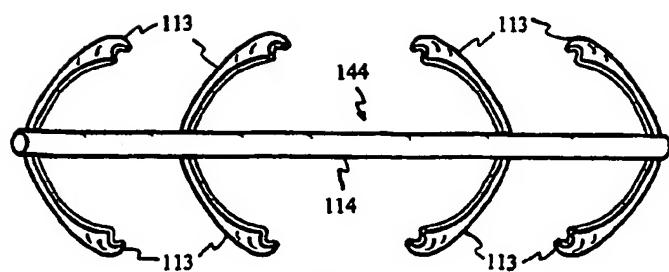


Figure 19

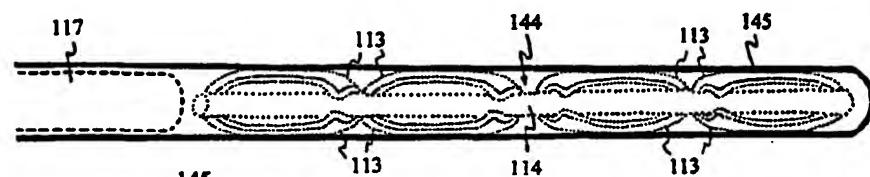


Figure 20

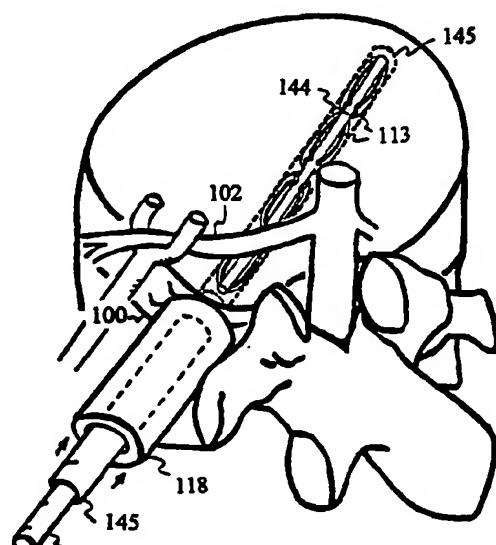
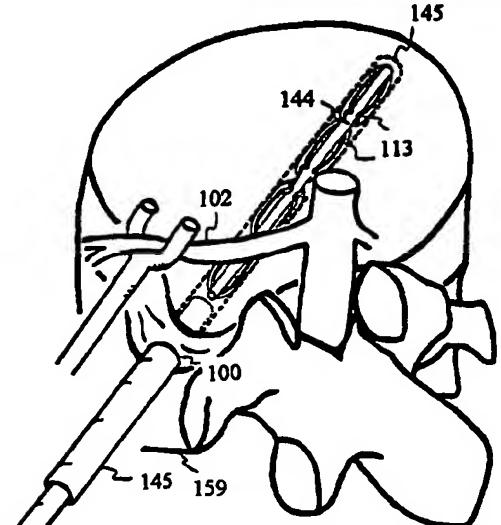


Figure 21

Figure 22

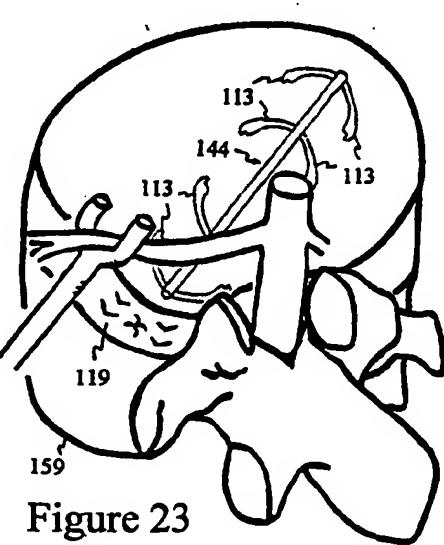
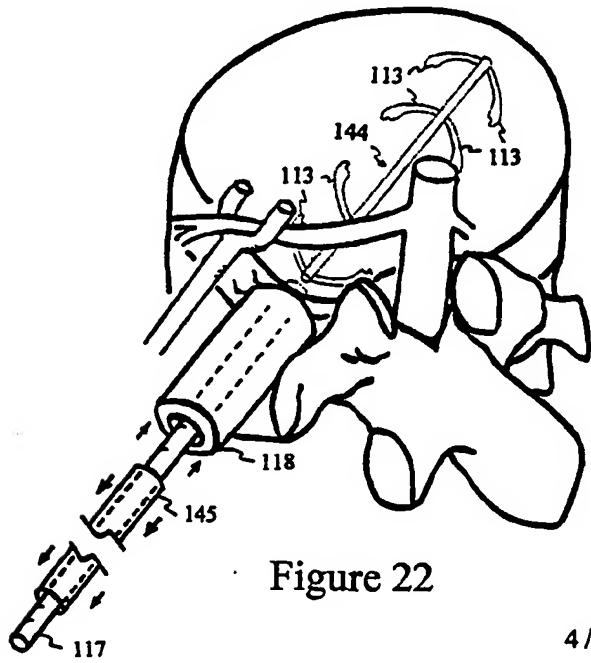


Figure 23

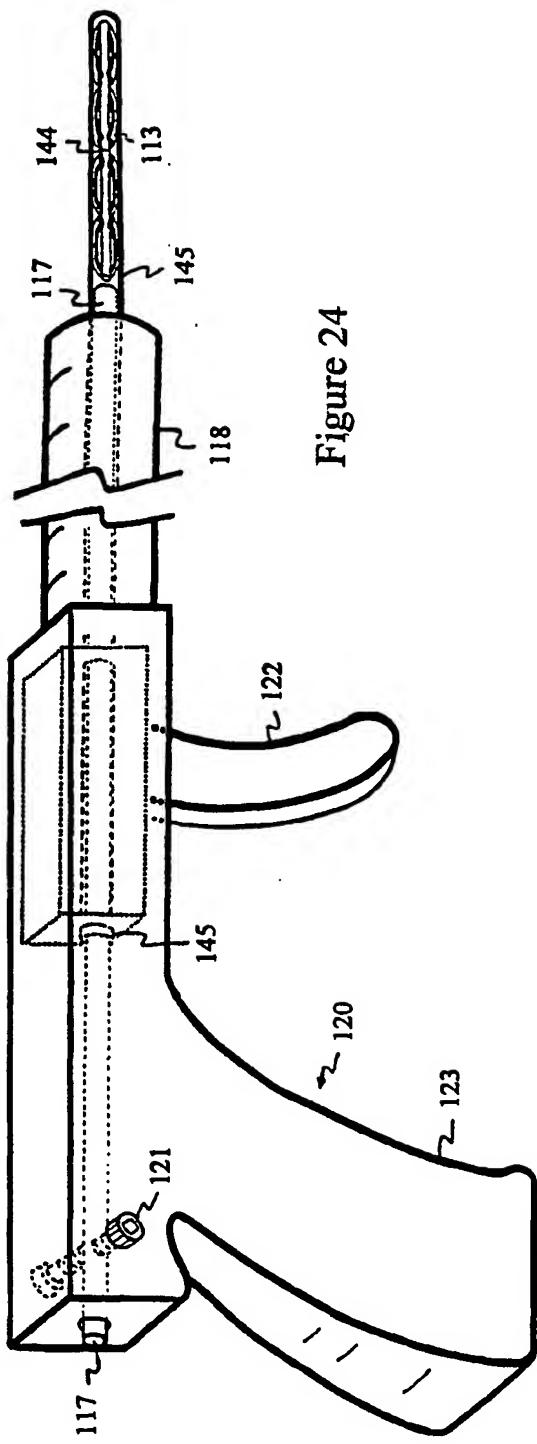


Figure 24

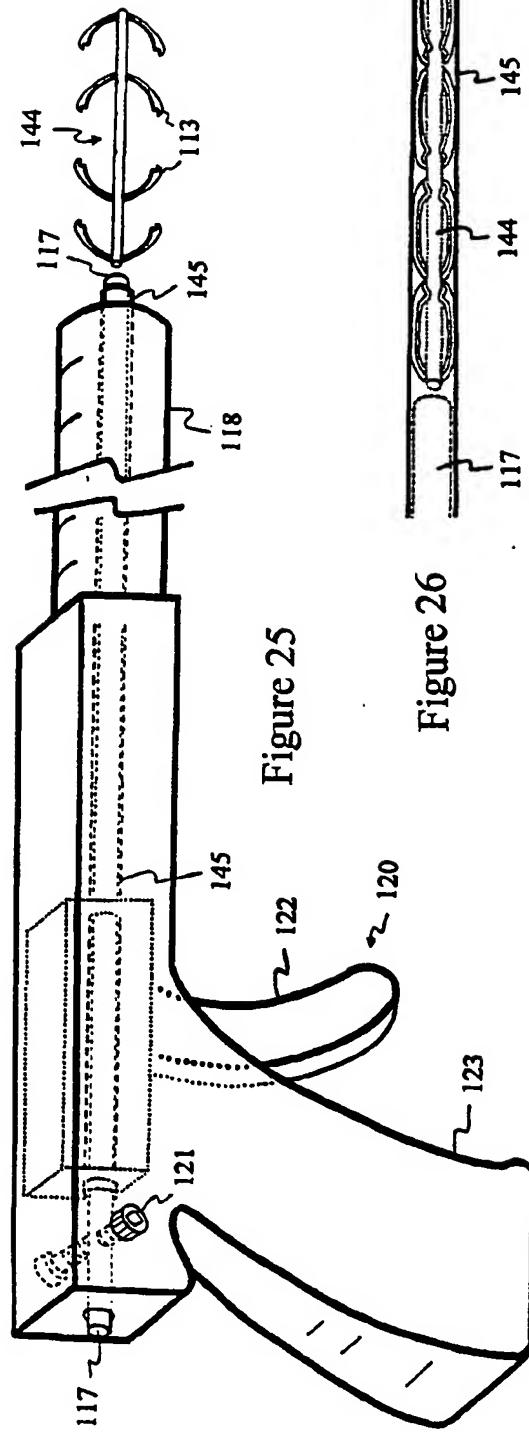


Figure 25

Figure 27

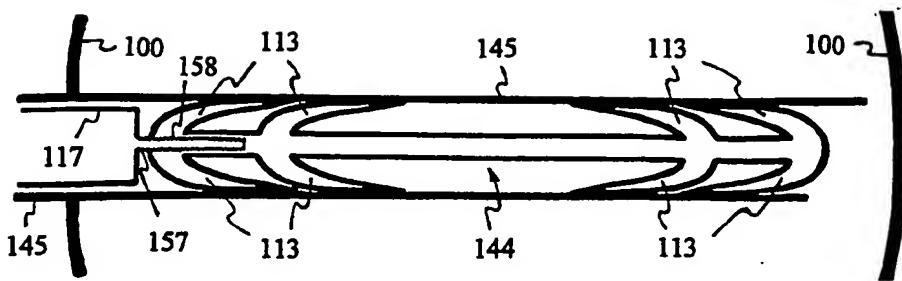


Figure 28

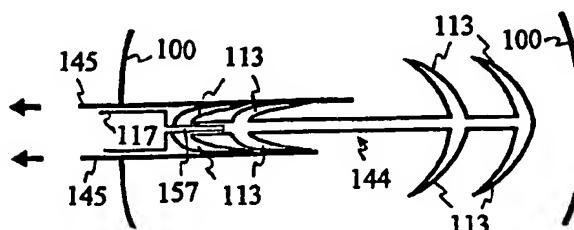


Figure 29

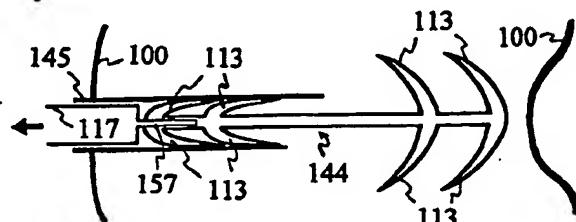


Figure 30

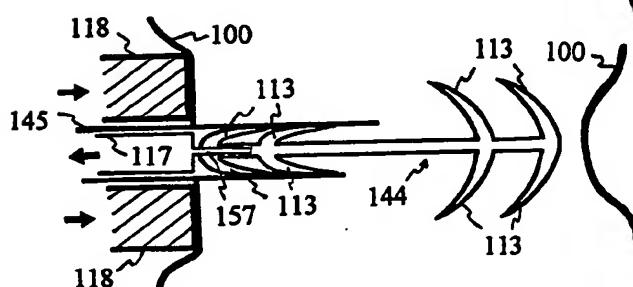


Figure 31

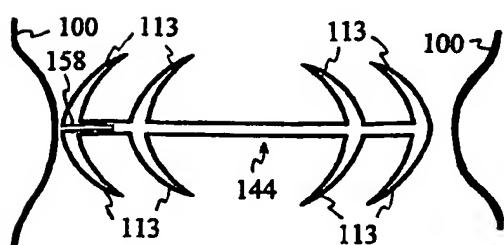
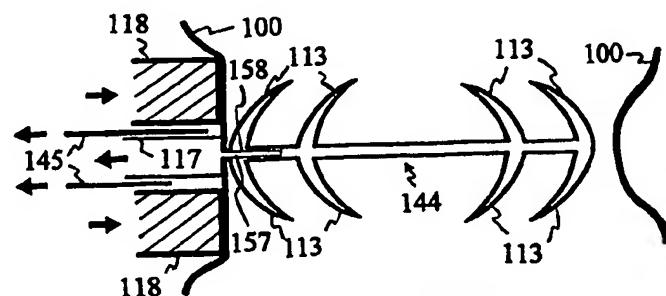
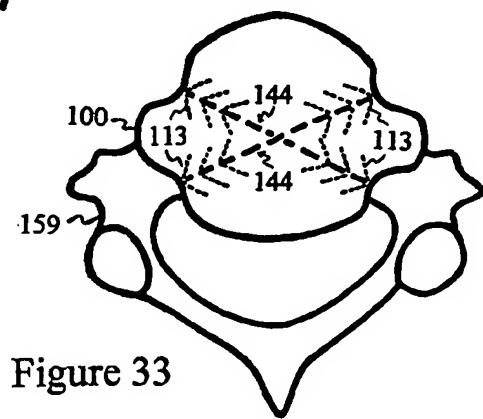


Figure 32



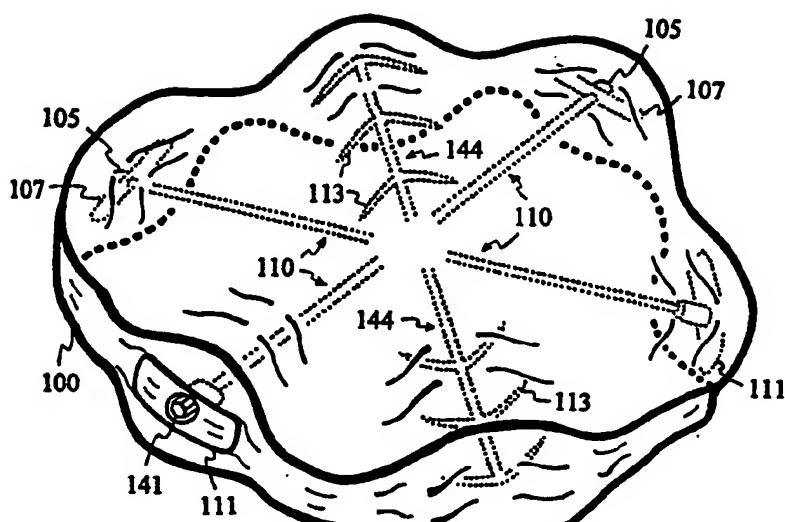


Figure 34

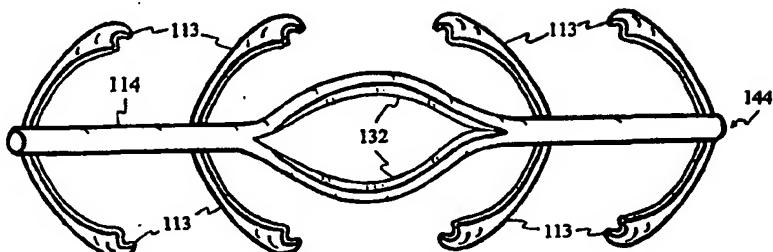


Figure 35

Figure 36

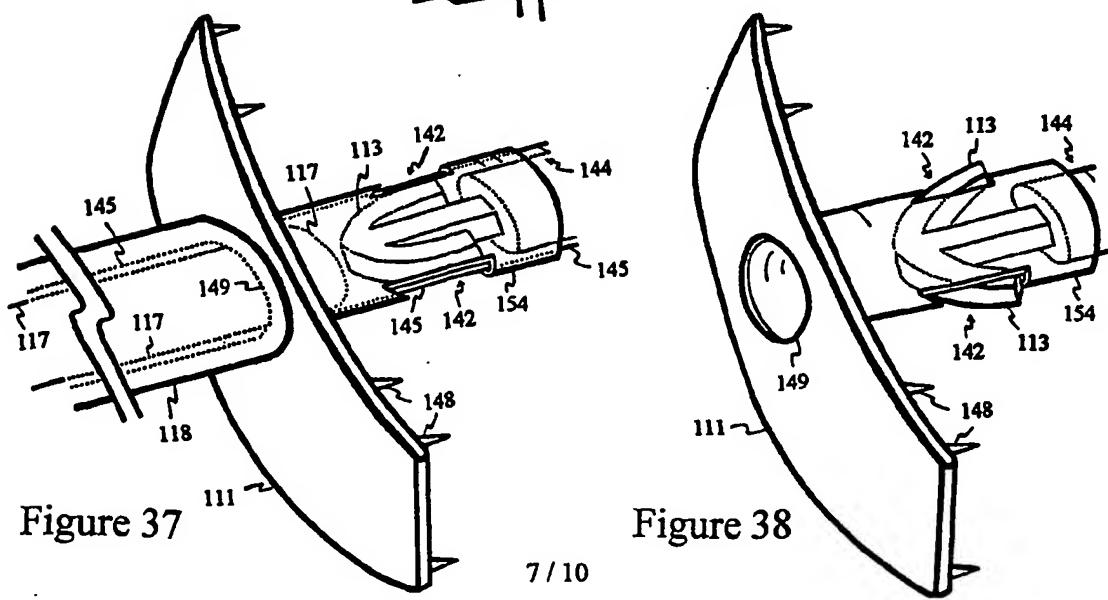
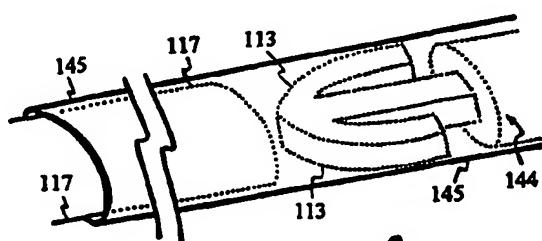


Figure 38

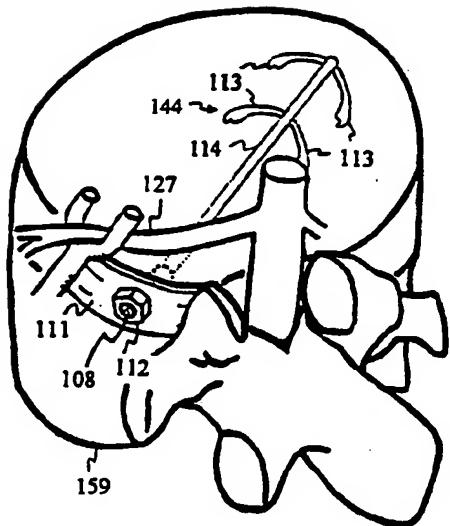


Figure 39

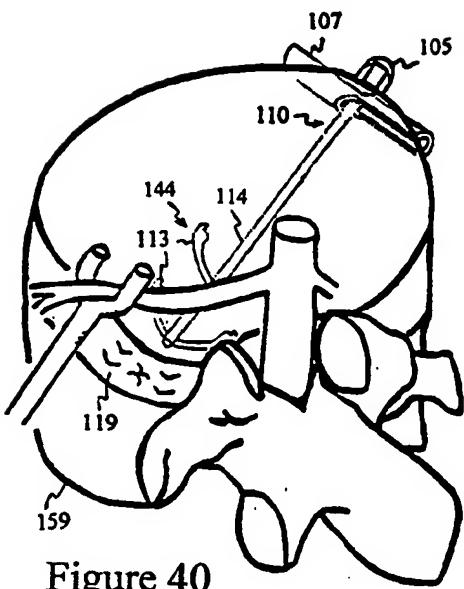


Figure 40

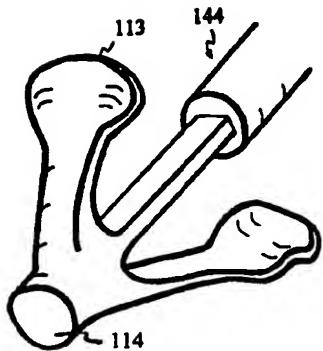


Figure 41

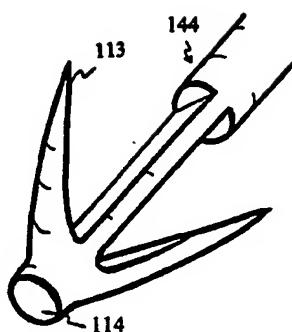


Figure 42

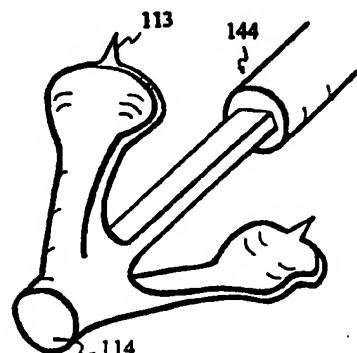


Figure 43

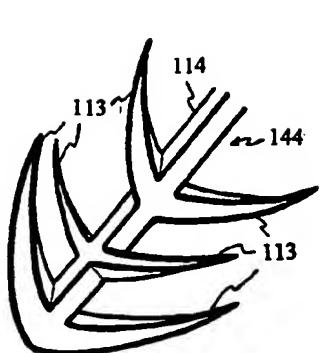


Figure 44

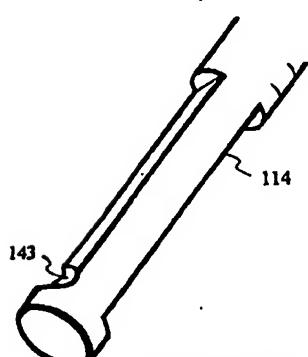


Figure 45

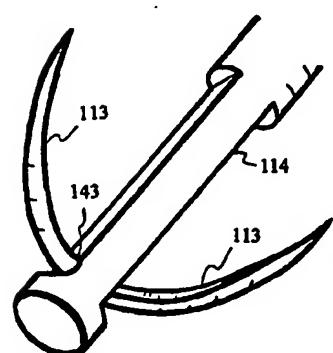


Figure 46

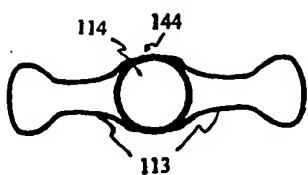


Figure 47

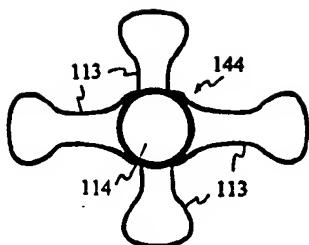


Figure 48

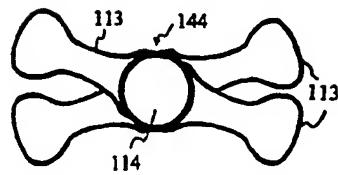


Figure 49

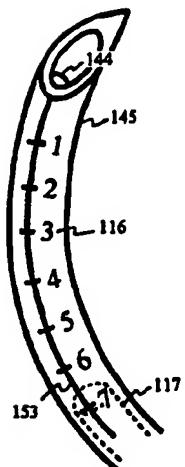


Figure 50

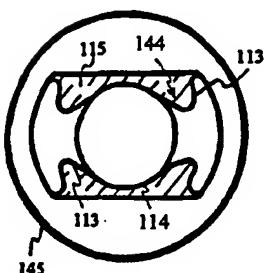


Figure 51

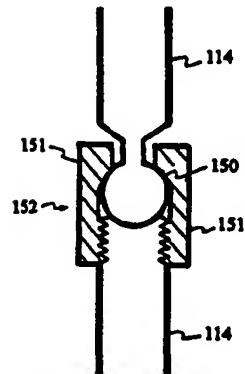


Figure 52

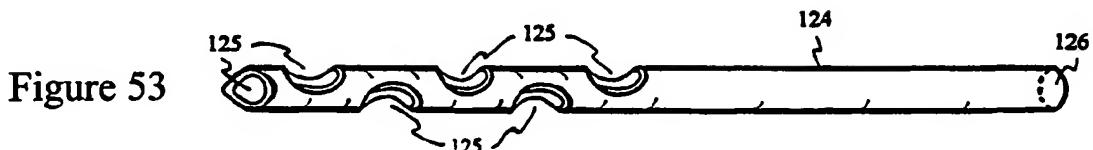


Figure 53

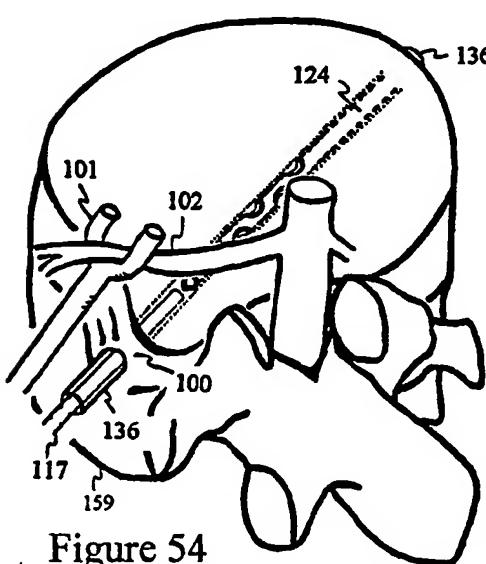


Figure 54

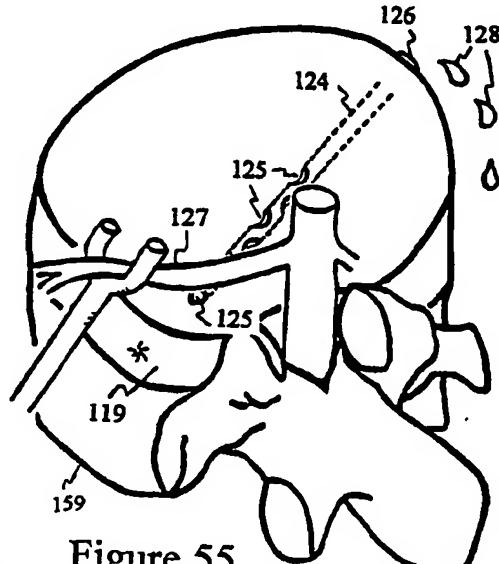
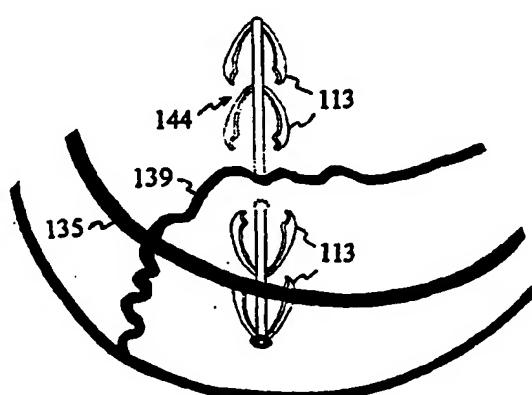
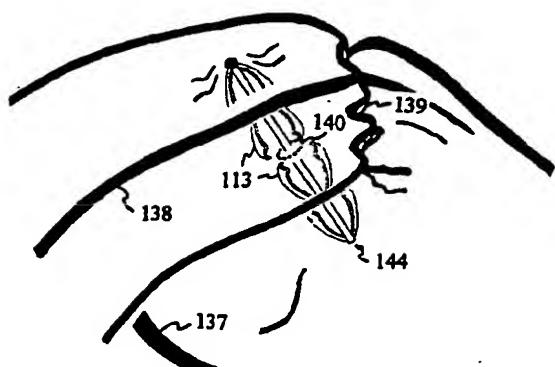
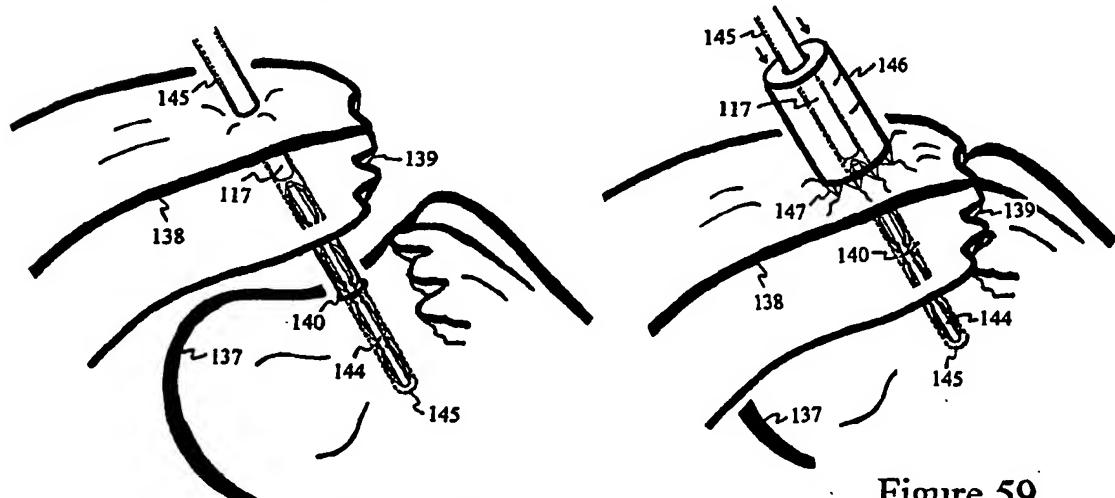
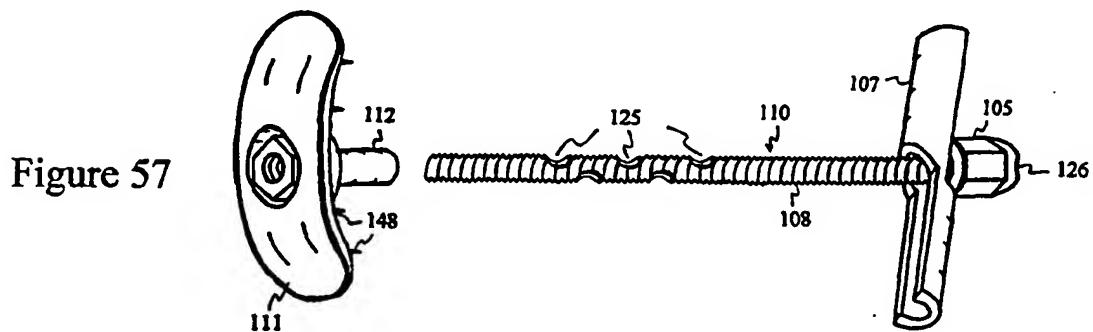
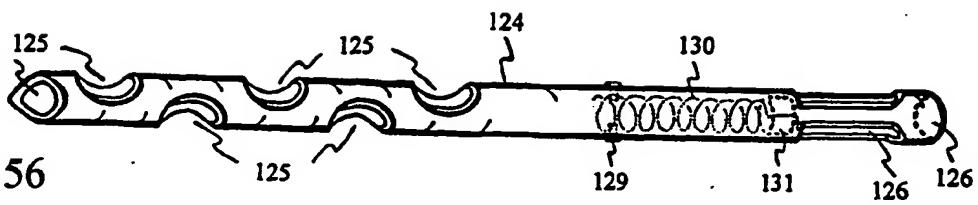


Figure 55



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/24921

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/70 A61B17/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-------------------------------------|
| A | US 2 485 531 A (W.DZUS AND G.S.KING) 18 October 1949 (1949-10-18) figures 1,3,6,7 --- | 1,2, 8-12,14, 17,18, 24,37 |
| A | WO 95 31946 A (SMITH & NEPHEW) 30 November 1995 (1995-11-30) page 1, line 3 -page 2, line 15 --- | 1,16,26, 27,37,39 |
| A | US 5 893 850 A (V.V.CACHIA) 13 April 1999 (1999-04-13) abstract; figures 1,8 --- | 1,2,10, 15,24,37 |
| A | WO 99 37219 A (ORTHODYNE) 29 July 1999 (1999-07-29) page 26, line 10 -page 27, line 11; figures 12A-12E ----- | 1,2,10, 24,26,37 |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed Invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed Invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

22 February 2001

Date of mailing of the International search report

21.06.01

Name and mailing address of the ISA
European Patent Office, P.B. 5618 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer

NICE P.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/24921

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: **28-36, 40-41, 95-115, 126-131**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple Inventions in this International application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-27, 37-39

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-27,37-39

Compression device for herniated intervertebral disc

2. Claims: 42-94

Tissue fastening device with resilient clamping elements

3. Claims: 116-125

Drain tube for herniated intervertebral disc

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/24921

| Patent document cited in search report | | Publication date | Patent family member(s) | | Publication date |
|--|---|------------------|-------------------------|------------|------------------|
| US 2485531 | A | 18-10-1949 | NONE | | |
| WO 9531946 | A | 30-11-1995 | AU 2621295 A | 18-12-1995 | |
| | | | DE 19581655 T | 28-05-1997 | |
| | | | GB 2303555 A | 26-02-1997 | |
| | | | JP 10503667 T | 07-04-1998 | |
| | | | US 6187048 B | 13-02-2001 | |
| US 5893850 | A | 13-04-1999 | NONE | | |
| WO 9937219 | A | 29-07-1999 | US 6068648 A | 30-05-2000 | |
| | | | AU 2461799 A | 09-08-1999 | |
| | | | EP 1051114 A | 15-11-2000 | |